The DECIDE Study: Dementia carers making informed decisions

Kathryn Louise Lord

Division of Psychiatry

Faculty of Brain Sciences

University College London

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Principal Supervisor: Dr Claudia Cooper (CC)

Second Supervisor: Professor Gill Livingston (GL)

Declaration

I, Kathryn Louise Lord confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Date

Kathryn Louise Lord

Acknowledgements

Firstly, I would like to thank my supervisors Dr Claudia Cooper and Professor Gill Livingston. They both provided invaluable support and advice throughout my PhD and I am constantly inspired by and in awe of their dedication and drive to improve the lives of people with dementia and their families.

Secondly, I am extremely grateful to all members of staff at the memory clinics who recruited participants on my behalf and would like to thank all study participants for their time and contribution to my PhD, without whom this would not have been possible.

Finally I would like to thank my wonderful colleagues, friends and family. There are too many people to mention who have provided endless cups of tea, laughs and encouragement throughout the last two and a half years and to all of you, I hope I can repay the favour someday. I'd like to personally thank Sarah, Nicki, Penny and Karen for advice, proof reading and everything in between. My fantastic parents, Gill and David, are the most loving, generous people I know. They make me feel like anything is possible if you work hard enough and I strive every day to make you both proud. To my Fred, thank you for putting up with me during this PhD journey, your love and support means the world to me, here's to the next chapter of our lives!

I would like to dedicate this PhD to my grandma, Beryl. She was the kindest person I have ever known and inspired me to want to improve the lives and care of the elderly.

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Abstract

Background: Individuals with dementia may require increased care but lose decision-making capabilities. Relatives report decisional conflict when making such decisions on behalf of the person with dementia.

Aim: To develop and test the acceptability and feasibility of a decision aid (DECIDE manual) to reduce decisional conflict of family carers about decisions regarding their relative with dementia's future place of residence.

Methods: I conducted a systematic literature review; individual interviews with people with dementia, family carers and healthcare professionals, then developed the DECIDE manual. Following piloting, I tested the manual in a randomised controlled trial with family carers currently making the decision about where their relative with dementia should live. Primary outcomes were the proportion of participants who found DECIDE relevant and useful. Secondary outcomes were differences in group scores on total Decisional Conflict Scale and sub-scales 10 weeks later. I then asked carers about potential improvements to DECIDE.

Results: I developed an interactive manual for carers to complete with professionals. I recruited and randomised 41 carers (21 control, 20 intervention). All participants found the DECIDE manual useful and relevant. The intervention group had reduced total decisional conflict compared to controls (mean difference = -11.96, 95% confidence interval [-20.10, -3.83], p = .005). Carers felt more informed about available options, more certain about the decision and clearer about their personal values. Carers found DECIDE did not address disagreement among family members and negotiating services.

Conclusion: Carers found the DECIDE manual acceptable and useful. Whilst the small sample size means quantitative results must be cautiously interpreted, they are promising. Carers valued the decision aid's structured information and had less conflict. Future research into addressing the additional barriers to this difficult decision and further trials of the effect of the DECIDE manual in a real world setting and subsequent implementation are logical next steps.

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Statement of personal contribution

As principal researcher for this study, my contributions were as follows:

- I designed and wrote the study protocols for phase one and two with input from academic supervisors.
- I applied for and obtained National Research Ethics Service (NRES) and local trust research and development approvals for both phases of the study.
- For my systematic review, I conducted the literature searches, data extraction, study quality appraisal and prepared the first draft of the paper.
- I conducted all individual qualitative interviews and co-facilitated the healthcare professional focus groups with another researcher, Hannah Deakin. I transcribed, coded and analysed all the qualitative data that was also independently coded by another researcher, Sarah Robertson.
- For phase two, I wrote and delivered the DECIDE intervention. I recruited and conducted all baseline and follow-up quantitative assessments, and conducted the quantitative statistical analysis. I collected, transcribed, coded and analysed all the qualitative data, which was also independently coded by another researcher, Nicola White.
- I wrote all the content of this thesis.

List of abbreviations

CI = Confidence Interval

DCS = Decisional Conflict Scale

HADS = Hospital Anxiety and Depression Scale

ICD = International Classification of Diseases

IMCA = Independent Mental Capacity Advocate

IPDAS = International Patient Decision Aids Standards

MRC = Medical Research Council

n = Number of participants

ODSF = Ottawa Decision Support Framework

p = Level of significance

RCT = Randomised Controlled Trial

REC = Research Ethics Committee

SD = Standard Deviation

Chapter 1 Introduction

Dementia is a major cause of disability and dependency among older people; worldwide an estimated 46.8 million people currently have dementia and 9.9 million new cases are diagnosed each year (Prince *et al.*, 2015). Dementia affects the person diagnosed, their families, caregivers and the wider society. The cost of dementia is vast and it significantly impacts every health and social care system across the world (Wimo and Prince, 2010). The overall economic impact of dementia in the United Kingdom (UK) alone is £26.3 billion per year; 44% of this total cost is contributed by the work of unpaid family carers (Prince *et al.*, 2014).

A fundamental principle of healthcare systems in most developed countries is enabling and empowering individuals to make choices about the care they receive and where they receive it. It is enshrined in the National Health Service (NHS) constitution which establishes the principles and values of the NHS in England (Department of Health, 2015). As the severity of dementia increases, people with the illness are often unable to make decisions about their care and, therefore, rely on family members and friends to assist or make proxy decisions and communicate their previous wishes. Planning and making decisions about one's own future can be challenging; having to make these very important decisions for another person may be more difficult still. The uncertainty of how dementia will progress compounds this difficulty (Caron *et al.*, 2005).

In the CHOICE study, family carers of people with dementia were asked to identify difficult decisions they had needed to make on behalf of their relative (Livingston *et al.*, 2010). Participants reported particular difficulties with decisions around care transitions; for instance, from full independent living to paid home care, and, in particular, the decision about when a move to 24-hour care might be needed (Livingston *et al.*, 2010). Decision-making regarding the future and preferences for place of care can be particularly difficult and stressful (Butcher *et al.*, 2001), in many instances requiring individuals to consider a number of unknown hypothetical

experiences with various potential outcomes. Many people would wish or intend to care for their relative at home throughout the disease duration. This may become unfeasible due to the consequences of more severe cognitive impairment or complex health needs; including neuropsychiatric symptoms such as aggression or insomnia (Onishi *et al.*, 2005). In contrast to some decisions, such as those around end of life care, where there is often agreement between people with memory problems and their carers (Ayalon *et al.*, 2012), this major decision is often made contrary to the person with dementia's current or previous known wishes and frequently associated with feelings of failure or guilt (Livingston *et al*., 2010).

The James Lind Alliance identifies priorities for future research by collating the views of patients, carers and clinicians. One of the top ten priorities for dementia (2013) is identifying the optimal time to move a person with dementia into a care home setting; considering quality of life, trauma to the person with dementia, behaviour, physical function and costs. This prioritisation recognises the complexity of this decision, which is usually made by, or in consultation with, family carers (Kelly *et al.*, 2015). Despite place of care decisions being identified as a major source of stress for carers of people with dementia, to our knowledge, no intervention designed to reduce this distress has been formally evaluated. Decision aids have been shown to improve knowledge, reduce decisional conflict and encourage individuals to become more involved in making a range of health decisions (Stacey *et al.*, 2014). In this study, I developed a decision aid (the DECIDE manual) and tested its feasibility. The DECIDE manual aims to assist healthcare professionals to support dementia family carers making proxy decisions about living arrangements and future place of care.

The structure of this PhD and the development of the DECIDE manual is in line with the Medical Research Council (MRC) developing and evaluating complex interventions guidance (2008). This guidance advises a process of: identifying the evidence base and developing the theory; piloting the work and testing procedures; evaluating the process and its effectiveness; and then, implementing the intervention (Figure 1). According to

the MRC guidance, few interventions are truly simple. In developing the DECIDE manual, specific complexities I needed to consider were the variability of the population and the individual nature of the issues being discussed. In this PhD, the carers recruited all experienced their caring role differently; in terms of both their relationship with their relative with dementia, the severity of that person's dementia, their level of need and living situation at the time of participation in the research.

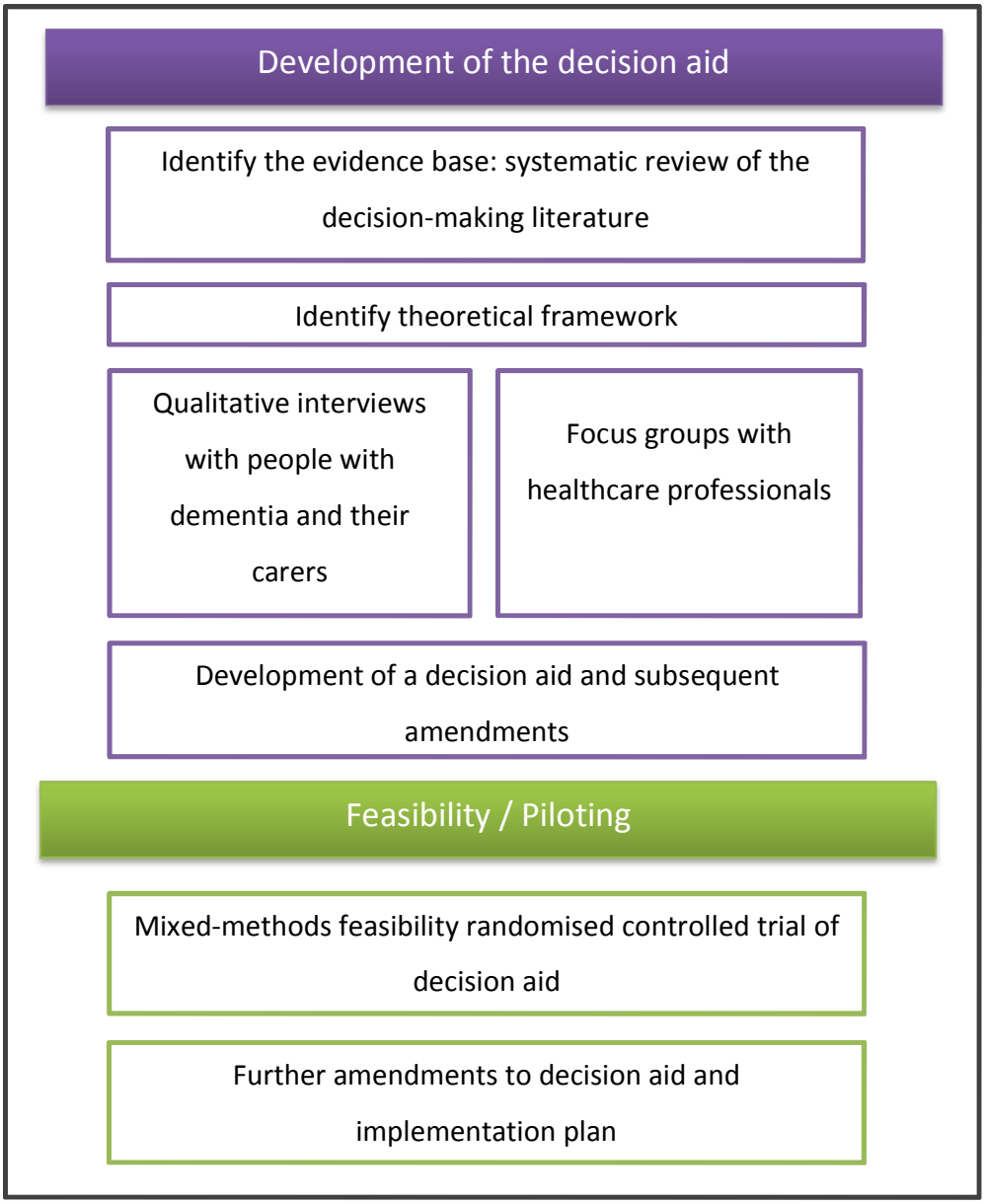
Figure 1: MRC guidance: key elements of the development and evaluation process

1.1 Thesis structure

Figure 2 illustrates how elements of my thesis map on to the MRC developing and evaluating complex interventions guidance. In Chapter one, I describe the rationale for carrying out this PhD and introduce the topics of dementia, family carers, place of care

and decision-making. In Chapter two, I systematically review the evidence base around dementia family carer proxy decision-making regarding place of care. In Chapter three, I state my research aims and objectives. In Chapter four, I detail the theoretical basis of decision aids and explain my choice of theoretical framework for my decision aid, the Ottawa Decision Support Framework (O'Connor *et al.*, 1998). In Chapter five, I describe phase one of my research programme; the method and results of qualitative interviews with people with dementia and their family carers to inform development of the DECIDE manual. In Chapter six, I describe how I developed the manual, further informed by the views of healthcare professionals, elicited in focus groups. In Chapter seven, I describe the mixed methods used for my feasibility randomised controlled trial comparing the use of the decision aid to usual care. In Chapters eight and nine, I detail the quantitative and qualitative results of the feasibility trial. Throughout Chapters five, six and nine, I describe how I iteratively developed the DECIDE manual. In Chapter ten, I discuss my findings from the feasibility randomised controlled trial in context, the strengths and limitations of the study, alternative study design and critique the decision aid against the International Patient Decision Aid Standards checklist (Elwyn *et al.*, 2006). In Chapter eleven, I discuss an implementation plan and future research directions. Finally, in Chapter twelve, I list my main conclusions. The appendix contains my ethics and R&D permissions, all study materials (information sheets, consent forms, topic guides and the DECIDE manual) and publications from my thesis; my systematic review, published in International Psychogeriatrics (Lord *et al.*, 2015) and my qualitative data and decision aid development in BMC Geriatrics (Lord *et al.*, 2016). I have been accepted to present my findings from my feasibility randomised controlled trial at the Alzheimer's Association International Conference (AAIC) 2016 and I will be submitting this data for publication in the next few months.

Figure 2: Thesis elements mapped onto the MRC guidance



1.2 Dementia

Dementia is defined by the International Classification of Diseases (ICD-10) (WHO, 1992) as "a syndrome due to disease of the brain, usually of a chronic or progressive

nature, in which there is disturbance of multiple higher cortical functions, including memory, thinking, orientation, comprehension, calculation, learning capacity, language and judgement. The impairments of cognitive function are commonly accompanied, and occasionally preceded, by deterioration in emotional control, social behaviour, or motivation". There are a number of types of dementia, with Alzheimer's disease the most common, accounting for approximately 62% of cases. Other common types of dementia are vascular dementia, accounting for approximately 17% of cases, mixed dementia (10% of cases), dementia with Lewy bodies (4% of cases) and Frontotemporal dementia (2% of cases) (Prince *et al.*, 2014). In the UK there are approximately 815,000 people with dementia (Prince *et al.*, 2014) and one in three people over the age of 65 will develop dementia by the time they die (Department of Health, 2012). There is currently no cure for dementia but pharmacological and non-pharmacological interventions can lessen symptoms and improve the patients' and their family carers' lives (Cooper *et al.*, 2014; Madhusoodanan and Ting, 2014; LivingstonKelly *et al.*, 2014).

1.3 Family carers

1.3.1 Epidemiology

In the 2011 Census, approximately 5.8 million people reported that they were providing unpaid care to others in England and Wales (Office of National Statistics, 2013). Family carers provide essential support and care to their relative or friend to enable them to continue living in their own homes. Greater recognition of the demands placed on family carers is reflected in recent government policy. In England, the Care Act (Department of Health, 2014) places responsibility with local authorities to assess all carers' need for support and the impact of this caring role on their own lives.

As the general population ages and life expectancy increases, the incidence of dementia and consequently the numbers of individuals caring for a person with

dementia is rising. In the UK, approximately 540,000 people provide care to a friend or family member with dementia (Prince *et al.*, 2014).

1.3.2 Caregiver burden

Caregiver burden has been defined as 'the extent to which caregivers perceive that caregiving has had an adverse effect on their emotional, social, financial, physical, and spiritual functioning' (Zarit *et al.*, 1986). A review of the literature concluded that the risk factors for experiencing greater caregiver burden include female sex, low educational attainment, residence with the care recipient, higher number of hours spent caregiving, depression, social isolation, financial stress and lack of choice in being a caregiver. The burden is also greater at times of care transitions, such as from hospital to home (Adelman *et al.*, 2014). Carers of people with dementia experience greater strain and distress than carers of older people with other conditions (Moise *et al.*, 2004). Being a dementia carer is also associated with higher rates of anxiety and depression (Mahoney *et al.*, 2005).

When carers of people with dementia are well supported, they provide better care for their relative or friend and report greater well-being (Ablitt *et al.*, 2009). Studies have highlighted the emotionally rewarding and positive aspects of dementia caregiving (Lloyd *et al.*, 2014; Cheng *et al.*, 2015). In the START trial, providing information and emotional and psychological support to change coping strategies improved carer mental health and quality of life and was cost-effective (Livingston *et al.*, 2013; LivingstonBarber *et al.*, 2014).

Throughout this thesis, the term 'carer' will be used to refer to an unpaid family member or friend who provides assistance or care to the person with dementia.

1.4 Place of care

Two-thirds of people with dementia currently live in the community (Prince *et al.*, 2014). Most people with mild dementia live in their own homes, but as the disease progresses, care needs increase and may necessitate a move to a long-term care facility, such as a residential or nursing home. Recent estimates suggest that approximately 80% of care home residents have dementia or 'significant memory problems' (Quince, 2013). Longitudinal predictors of care home placement in old age include death of one's spouse, dementia and substantial mobility impairments (Hajek *et al.*, 2015). A third of individuals with dementia who go into such a facility will do so following a crisis; for example, a fall and subsequent hospital admission (Alzheimer's Society, 2009). People with dementia are 20 times less likely over a one year period to be admitted to a care home if they live with their family carer (Banerjee *et al.*, 2003).

A 'Key Commitment' outlined in the Prime Ministers Dementia Challenge (Department of Health, 2012) is to build and create more 'dementia-friendly' communities to enable individuals to remain at home and living in their communities for as long as possible. The aim of the Prime Minister's Dementia Challenge is for half of citizens to live in Dementia Friendly Communities by 2020. These are communities which aim to ensure that people with dementia are empowered to aspire high and feel confident, knowing they can contribute and participate in activities meaningful to them.

1.5 Decision-making

Respect for an individual's autonomy is a key principle in biomedical ethics, ensuring that patients are allowed the opportunity to make choices regarding which healthcare interventions they do or do not want to receive. The goal in decision-making is to choose healthcare services that increase the chance of health outcomes of value whilst minimising the chances of undesired consequences based on the best available scientific evidence (O'Connor *et al.*, 2003). Many health and social care decisions have

no single 'best' choice. People approach health and social care decisions differently, and these processes have implications for the care or treatment that is ultimately received. Wolfs *et al.* (2012) differentiated three styles for making healthcare decisions: individuals who want a complete overview of the options available and will research these and make decisions independently; those who want a complete overview of options as well but with more guidance from health care professionals; and those who rely solely on the 'competent judgement' of health care professionals.

Patients and carers may need to choose between a number of options when making decisions about future care choices based on their values and preferences and the information provided. People with dementia usually want to stay in their own homes for as long as possible (Samsi and Manthorpe, 2011). As they become more impaired, problems and risks, many unanticipated, might arise which may indicate a move to a more supported living facility such as a care home is advisable. By this point, the person with dementia may have lost capacity to decide when this move should take place or not want to be involved in the decision-making process (Siminoff and Fetting, 1991).

1.5.1 Mental capacity

Legal frameworks provide structure for decision-making when an individual loses the ability to make a particular decision for themselves. In England and Wales, if a person lacks capacity to make their own decisions, the Mental Capacity Act (2005) states that (except when a valid advanced directive is in place) a relative who has been given Lasting Power of Attorney makes such decisions. If there is no Lasting Power of Attorney, the closest relative must be consulted by healthcare professionals and their views only disregarded if they do not seem to be in the patient's best interest. The relative consulted is asked to consider the wishes of the individual prior to their loss of capacity as well as their current wishes and best interests. These frameworks place relatives in a central role in the decision-making process. In instances where an individual has no relative or friend who can be consulted, an Independent Mental

Capacity Advocate (IMCA) can be called upon to safeguard the rights of people without capacity.

1.5.2 Advanced decisions

An advanced decision to refuse treatment means an individual can make a decision now about refusing specific types of treatments or medical interventions in the future. If this advanced decision to refuse treatment is valid and applicable to the situation at hand, then healthcare professionals must follow it. Advanced statements are more general decisions describing individuals' wishes and preferences about future treatment and care, such as, where a person would like to live and be supported. Additionally, in an attempt to try and document wishes around care, Advanced Care Plans were established as part of the End of Life Care Programme hosted by the NHS. However, few individuals complete the advanced care plan documentation, and those completed often do not determine subsequent healthcare service use (Robinson *et al.*, 2012). Additionally, a systematic review found a lack of evidence supporting the use of Advanced Care Plans in people with dementia; most decisions about place of care for people with dementia who lack capacity are made by family carers and healthcare professionals, without an Advanced Care Plans being in place (Harrison-Dening *et al.*, 2011).

1.5.3 Healthcare professionals involvement

Maintaining the person with dementia's autonomy is a key principle in decision-making and shared decision-making is considered best practice (Department of Health, 2012). Shared decision-making is a collaborative process where decisions are made by clinicians together with the patient (Stacey *et al.*, 2014), based on the doctor's knowledge and the patient's preferences. Healthcare professionals agree that involving carers in decisions to consider what the patient would have wanted improves care, although some question the accuracy of surrogate decision makers in predicting patients' treatment preferences (Shalowitz *et al.*, 2006; Torke *et al.*, 2008). Carers' level

of involvement is often dependent on the individual staff member approaching them about decisions and lacks consistency (Walker and Dewar, 2001). Carers report feeling strained and confused when making proxy decisions and needing more information, support, person-centered guidance and constructive discussion (Samsi and Manthorpe, 2013). Family carers frequently cite interventions by healthcare professionals as pivotal to their experiences, both positive and negative, of decision-making (Walker and Dewar, 2001; Torke *et al.*, 2013). Therefore it is critical that professionals have the skills to support family carers to make these challenging decisions.

1.5.4 Decision aids

Active involvement of patients in shared decision-making with clinicians is a quality statement in several of the National Institute for Health and Care Excellence (NICE) Clinical Guidelines including the Service user experience in adult mental health services guidance (2011), the Patient experience in adult NHS services guidance (2012) and the Medicines optimisation guidance (2016). All of these guidelines explicitly refer to the use of decision aids to help patients make informed healthcare decisions.

More than 500 patient decision aids currently exist (Elwyn *et al.*, 2006). Decision aids have been developed for healthcare scenarios ranging from medical therapies for cancers and heart conditions, to diagnostic tests and preventative therapies (Stacey *et al.*, 2014). These aids are paper, web or video based resources that provide structured information on the available options and their harms and benefits to assist individuals in determining their values in order to make an informed choice. These decision aids do not replace the role of the healthcare professional; they are a tool to enhance the doctor-patient interaction. Decision aids can be used when: there is more than one reasonable option; no option has a clear advantage in terms of health outcomes or, each option has benefits and harms that a patient may value differently (Stacey *et al.*, 2014). Decision aids differ from educational materials providing information on the topic because they guide individuals to consider and express their own personal values

and opinions. The goal is to make evidence-based decisions as far as possible, and for individuals to understand the balance of the risks and benefits of each option. Decision aids are an example of 'third-generation knowledge'; first-generation knowledge is knowledge derived from primary studies such as a randomised trial; second-generation refers to outputs such as systematic reviews of the literature; and third-generation are products that aim to present knowledge and information in a user-friendly and implementable way (Brouwers *et al.*, 2010). A recent Cochrane review concluded that decision aids improve people's knowledge regarding options, reduce their decisional conflict, encourage people to take a more active role in decision-making and facilitate risk assessment (Stacey *et al.*, 2014).

Few current decision aids are theory based (Durand *et al.*, 2008). I will discuss theories underpinning the development of patient decision aids in Chapter four, and explain the rationale for my decision to use the Ottawa Decision Support Framework (ODSF) (O'Connor *et al.*, 1998) as the theoretical basis for the DECIDE manual. The ODSF is one of the most commonly used and implemented theories, and decision support interventions guided by it are well suited for place of care decision-making (Murray *et al.*, 2004; Durand *et al.*, 2008). The goal of decision aids is to enable high-quality decisions. The International Patient Decision Aids Standards (IPDAS) collaboration agreed criteria for judging whether decision aids are high quality. The criteria list 'the things that you would need to observe in order to say that after using a patient decision aid, the way the decision was made was good and that the choice that was made was good'. The criteria include knowing the options available and their features and being clear about which matter most (Elwyn *et al.*, 2006). When evaluating decision aids, it would not be appropriate to use the decision made by the individual as the primary outcome as many of the healthcare related decisions people make are based on their own values and there is no right or wrong answer. In order to evaluate decision aids in line with the IPDAS criteria numerous measures have been developed with the Decisional Conflict Scale (DCS) (O'Connor, 1995) most commonly used (Stacey *et al.*, 2014). Decision-making about place of care for people with dementia is a

preference sensitive decision. The choices carers make are value-laden therefore sufficient information and emotional support is needed.

1.5.5 Decisional conflict

Decisional conflict has been defined as uncertainty about which course of action to take when the choice among competing actions involves risk, loss, regret or challenges to personal life values (North American Nursing Diagnosis Association, 1992). In lay terms, decisional conflict refers to the struggle one might face when trying to pick between options when there is no single 'best' choice.

Decisional conflict can arise due to inadequate knowledge, unclear values and lack of support, all potentially modifiable factors. Signs of decisional conflict include verbalised uncertainty about choices and the undesired consequences of alternatives; hesitancy between choices, decision regret and delayed decision-making (O'Connor, 1993; O'Connor *et al.*, 1999; Walker and Dewar, 2001). Other signs include verbalised distress while attempting decision-making, self-focusing, physical signs of distress or tension and questioning personal values and beliefs while attempting to make a decision.

High levels of decisional conflict may lead to hyper-vigilant coping strategies where individuals make hasty decisions that give immediate relief from the stress and conflict, however, in doing so may overlook the potential consequences of such a decision. Decisional conflict can be lowered with decision supporting interventions (Stacey *et al.*, 2014). Following information about options, benefits, risks and outcomes, individuals may feel they have made a better decision, meaning they feel that they have made a more informed, value-based decision, are more likely to stick with their choice and are more satisfied with the decision (O'Connor, 1993). Decisional conflict has been reported by carers in a variety of healthcare decision-making scenarios and strategies to reduce this conflict are needed (Stirling *et al.*, 2012; Graham *et al.*, 2015).

In the next chapter, Chapter two, I will outline and review the current evidence regarding barriers and facilitators to proxy decision-making by dementia carers, and interventions to facilitate this decision-making.

Chapter 2 Systematic review

In January 2014, I carried out a systematic review to identify barriers and facilitators to carer proxy decision-making and the effectiveness of interventions designed to help dementia family carers make these decisions. This was published by International Psychogeriatrics (Lord *et al.*, 2015) (Appendix 1). For this thesis, I updated the search using the same criteria for papers published from 1st February 2014 to 15th January 2016, and incorporated these findings below.

2.1 Method

2.1.1 Search strategy

I searched Medline for papers published with no restrictions on date up to 31st January 2014, in English using the terms '*dementia*' or '*Alzheimer*', combined with '*carer*' or '*caregiver*' and '*decision*' or '*decide*' or '*substitute judgement*'. I only searched Medline as it is the most universally used starting point in health-realted systematic reviews and has greater discriminating power than the indexing of several other biomedical databases (Sampson *et al.*, 2006). I hand searched references of included papers for any further papers that met the inclusion criteria. I updated the search on 15th January 2016.

2.1.2 Inclusion and exclusion criteria

I included all primary research, both qualitative and quantitative, that reported barriers or facilitators to decision-making about health and social care interventions by informal (family and friend) carers of people with dementia, or reported the effectiveness of an intervention that sought to facilitate the decision-making process. I excluded meeting abstracts, letters, literature reviews, case studies, editorials and correspondence. I read and screened all titles and abstracts of studies. My primary supervisor (CC) and I then

independently read all retained papers and decided to include or exclude papers by consensus.

2.1.3 Assessment of quality

CC and I rated the quality of papers independently, using six-item checklists for qualitative and quantitative papers developed by our group (Mukadam, 2011; Cooper *et al.*, 2014) from standardised assessment tools (Boyle, 1998) (See Table 1). Each item on the checklists scored one point so the possible quality scores were 0-6 with higher scores indicating better quality. CC and I discussed any discrepancies in quality scores and reached a consensus.

I set *a priori* criteria for defining higher quality studies. For quantitative studies we categorised papers as higher quality if they: clearly defined the target population, used standardised data collection methods and the measure(s) of proxy decision-making had known validity and reliability in the population studied (Table 1, criteria 1, 4, 5 and 6). For qualitative studies, we categorised papers as higher quality if they: used a clearly defined recruitment method and clearly stated inclusion and exclusion criteria, used standardised data collection and involved two or more independent raters in data analysis (Table 1, criteria 2, 3 and 5). For intervention studies, we categorised papers as higher quality if they: appropriately allocated participants to intervention and control groups, all participants who entered the trial were accounted for and they collected data and followed up all participants in the same way (Table 1, criteria 1, 3 and 4).

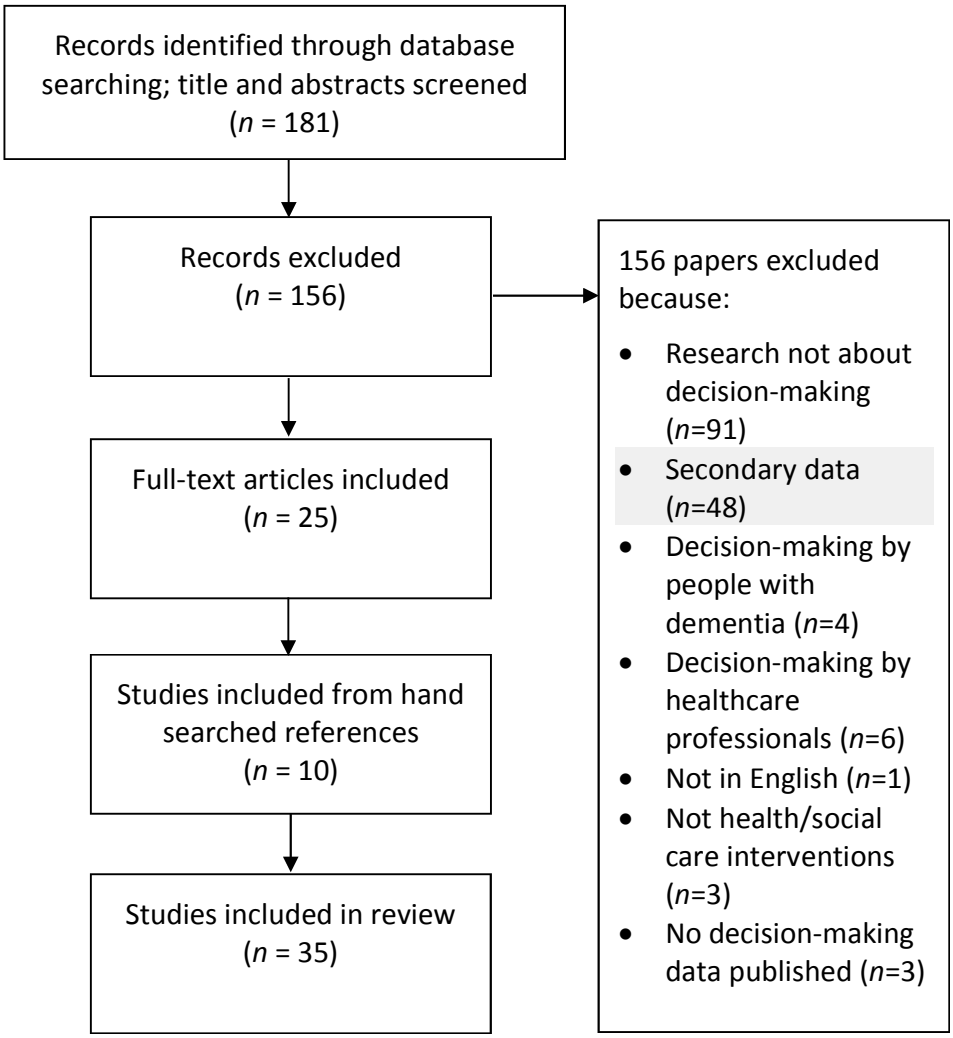
Table 1: Criteria used to rate quality of studies

Quality assessment tool for quantitative studies	Quality assessment tool for qualitative studies	Quality assessment tool for intervention studies
1) Was the target population defined by clear inclusion and exclusion criteria?	**1)** Were the aims of the research clearly stated?	**1)** Were participants appropriately allocated to intervention and control groups? Was randomisation independent?
2) Was probability sampling used to identify potential respondents (or the whole population approached)?	**2)** Was a clearly defined method of recruitment used and explicit inclusion / exclusion criteria described?	**2)** Were patients and clinicians, as far as possible, 'masked' to treatment allocation?
3) Did characteristics of respondents' match the target population i.e. was the response rate ≥80% or appropriate analysis included comparing responders and non-responders?	**3)** Was the process of data collection explained clearly? Was data collection standardised?	**3)** Were all patients who entered the trial accounted for and an intention-to-treat analysis used?
4) Were data collection methods standardised?	**4)** Did the researchers attain saturation of data?	**4)** Were all participants followed up and data collected in the same way?
5) Was the measure used valid?	**5)** Was the process of data analysis sufficiently rigorous i.e. ≥2 raters, some method of resolving discrepancies?	**5)** Was a power calculation carried out, based on one of our outcomes of interest?
6) Was the measure used reliable?	**6)** Have the findings been validated by participants?	

2.2 Results

I found 181 results in my search (of which 77 were from the updated search) and included 35 relevant papers (of which 5 were from the updated search) (Figure 3, PRISMA diagram of my combined search). 11/23 of the qualitative papers and 4/12 quantitative/intervention papers were categorised as higher quality. These results are summarised in Table 2 for qualitative papers, Table 3 for quantitative papers and Table 4 for intervention papers. I have described in sections 2.2.1 to 2.2.3.4, and in Table 5, the triggers, barriers and facilitators to decision-making identified.

Figure 3: PRISMA diagram



2.2.1 Factors that trigger decision-making by family carers

Four of the higher quality studies (Ducharme *et al.*, 2012; Butcher *et al.*, 2001; Caron *et al.*, 2006; Stephan *et al.*, 2015) and two of the lower quality studies (Caldwell *et al.*, 2014; Cohen *et al.*, 1993) interviewed family carers about making proxy decisions regarding moving a person with dementia to 24-hour care and identified factors that triggered the decision-making process. Ducharme *et al.* (2012) conducted 52 semi-

structured interviews with 18 family carers who had considered care home placement of their relative in Canada during the past year. This consideration of placement was sometimes due to the deterioration of the person with dementia's condition and at other times because the carer either found it difficult to continue caring or because their own health deteriorated. If the carer decided that the family member should remain at home they often commented that they would reconsider this if and when the care situation changed. Butcher *et al.* (2001) interviewed 30 family carers in the United States of America (USA) who had already made the decision to move their relative with dementia into a nursing home. Similarly to Ducharme *et al.* (2012) they found that the decision-making process was often triggered by a decline in the person with dementia's functioning and increased caring responsibilities. Similar triggers were identified by Caldwell *et al.* (2014) who interviewed 27 Australian carers of people with dementia, some of whom stated they made the decision to place their relative on the waiting list for nursing home placement due to realisation that they weren't coping. For others this decision was triggered by a specific incident such as a fall or a decline in the health of the carer or the person with dementia's condition.

One study explored what predicted decisions carers made about placements. More than half (51%) of 196 Canadian dementia carers, who initially planned on maintaining their relative at home, had moved them to a care home 18 months later. Doing so was associated with poorer carer health, greater burden and less enjoyment of caring (Cohen *et al.*, 1993). Spouses were significantly less likely to decide that the person they cared for needed to move to a care home, when compared with adult child carers.

Caron *et al.* (2006) interviewed 14 carers who had considered moving their relative with dementia to long-term care in the preceding six months in Canada, and identified three central processes in decision-making. These comprised: the carers' perceptions of their ability to provide care, their evaluations of their relatives' ability to make care decisions, and contextual factors, such as, the living environment, crises such as a fall or hospitalization and interactions with healthcare professionals. The average time

from carers' initial thoughts about placement to their relative moving to a care home was two years.

Stephan *et al.* (2015) conducted a cross-sectional survey with healthcare professionals and family carers in eight European countries regarding potential reasons for a person with dementia moving to a care home. The most frequent perceived impacts on carers' decisions were: caregiver burden, the caregiver being unable to provide care, neuropsychiatric symptoms, overall deterioration and care dependency in the person with dementia.

Table 2: Methodological characteristics and quality ratings of qualitative papers included

Study	Methodology	Source and country of carer recruitment	Decision studied	N	Validity criteria					
					1	2	3	4	5	6
Butcher *et al.* (2001)	Semi-structured interviews (Sampson *et al.*)	Nursing homes, United States of America (USA)	Placement decision	30	✓	✓	✓	✓	✓	X
Cairns (2012)	Semi-structured interviews	Local support groups, United Kingdom (UK)	Placement decision	5	✓	✓	X	X	X	X
Caldwell *et al*. (2014)	Semi-structured interviews	Nursing homes, Australia	Placement decision	27	✓	✓	✓	✓	X	X
Caron *et al*. (2006)	Semi-structured interviews	University geriatric units, Canada	Placement decision	14	✓	✓	✓	X	✓	X
Chang and Schneider (2010)	Semi-structured interviews	Gero-psychiatric clinic and Nursing homes, Taiwan	Placement decision	30	✓	✓	✓	✓	X	X
Chang *et al*. (2011)	Semi-structured interviews	Gero-psychiatric clinic and Nursing homes, Taiwan	Placement decision	30	✓	✓	✓	✓	✓	X
Chrisp *et al.*(2012)	Case studies	Memory clinic, UK	Values in treatment decisions	20	✓	X	✓	X	✓	X
Chrisp *et al.*(2013)	Case studies	Memory clinic, UK	Values in treatment decisions	20	✓	X	✓	X	✓	X
Ducharme *et al.* (2012)	Longitudinal semi-structured interviews	Previous study and the Alzheimer's Society, Canada	Placement decision	18	✓	✓	✓	✓	✓	X
Elliott *et al.* (2009)	Focus groups	Nursing homes, USA	Placement and end of life care decisions	39	✓	✓	✓	X	✓	X
Heinrich *et al.* (2003)	Longitudinal SSI and focus groups	Health-care agencies and newspaper adverts, Canada	Placement decision	20	✓	✓	✓	X	X	X
Kraijo *et al.* (2015)	Semi-structured interviews	Assessment agency, Netherlands	Placement decision	14	✓	✓	✓	✓	✓	✓
Kwon and Tae	Unstructured	Nursing homes, South Korea	Placement decision	16	✓	✓	✓	✓	✓	✓

(2012)	interviews									

Table 2 cont.: Methodological characteristics and quality ratings of qualitative papers included

Study	Methodology	Source and country of carer recruitment	Decision studied	N	Validity criteria					
					1	2	3	4	5	6
Livingston *et al.* (2010)	Semi-structured interviews and focus groups	Community healthcare settings, UK	Placement decision and end of life care decisions	89	✓	✓	✓	✓	✓	✓
Samsi and Manthorpe (2013)	Longitudinal semi-structured interviews	Community centres and Alzheimer's Society, UK	Values in treatment decisions	12	✓	X	✓	✓	✓	X
Smebye *et al.* (2012)	Semi-structured interviews and participant observation	Nursing services, sheltered housing and nursing homes, Norway	Involving people with dementia in decision-making	10	✓	X	✓	X	✓	X
Span *et al*. (2015)	Pre, post and during structured interviews	Through case managers, Netherlands	Evaluation of the DecideGuide	12	✓	✓	✓	X	✓	X
St-Amant *et al.* (2012)	SSI and participant observation	Faculty and community, Canada	Healthcare decisions	25	X	✓	✓	X	X	X
Sugarman *et al.* (2001)	Semi-structured telephone interviews	Six parent research projects in memory clinics, USA	Involving people with dementia in decision-making	49	✓	X	✓	X	✓	X
Torke *et al.* (2013)	Focus groups	Alzheimer Association support groups, USA	Healthcare decisions	32	✓	X	✓	✓	✓	X
Wackerbarth (1999)	Semi-structured interviews & focus groups	Alzheimer Association, USA	Values in treatment decisions	28	✓	✓	X	✓	X	✓
Walker and Dewer (2001)	Semi-structured interviews and non-participant observation	Respite / assessment ward of psychiatric unit, UK	Healthcare decisions	20	✓	✓	✓	X	✓	X
Wolfs *et al.* (2012)	Focus groups	Memory clinics / hospital, Netherlands	Values in treatment decisions	26	✓	✓	✓	X	✓	X

***Higher quality papers are in bold**

Table 3: Methodological characteristics and quality ratings of included quantitative papers

Study	Methodology	Source of carer recruitment	Primary outcome**	N	Validity criteria					
					1	2	3	4	5	6
Coetzee *et al.* (2003)	Cross-sectional questionnaire	Alzheimer's Society, UK	6 questions, 5 point Likert scale questionnaire	148	X	✓	X	✓	✓	✓
Cohen *et al*. (1993)	Longitudinal cross-sectional questionnaire	Community and medical teams, Canada	MBPC and The Burden Interview	196	✓	✓	X	✓	X	X
Hirschman *et al*. (2005)	Cross-sectional questionnaire	Memory clinic, USA	Yes/No treatment decision question, GDS and SCB	102	✓	X	X	✓	X	X
Karlawish *et al*. (2002)	Cross-sectional questionnaire	Memory clinic, USA	CDR and MMSE	74	✓	X	X	✓	X	X
Kwak *et al.* (2016)	Cross-sectional questionnaire	University based research registry, USA	End of life decision-making	141	✓	✓	✓	✓	✓	✓
Landau *et al*. (2011)	Cross-sectional self-administered questionnaire	Alzheimer's Society, Israel	4 point Likert scale questionnaire	94	✓	X	X	✓	X	X
Potkins *et al.* (2000)	Cross-sectional questionnaire	Old age psychiatry units and long-term care facility, UK	Yes/No/Unsure treatment decision questions	50	✓	✓	X	✓	✓	X
Stephan *et al*. (2015)	Cross-sectional questionnaire	Home care and community services, 8 European countries	Structured questions regarding reasons for institutionalisation	1160	✓	✓	X	✓	✓	✓
Tyrell *et al.* (2006)	Cross-sectional questionnaire	Community home help teams, France	6 questions, Likert scale questionnaire	21	✓	✓	X	✓	X	X

***Higher quality papers are in bold**

**MBPC = Memory and Behaviour Problem Checklist; GDS = Geriatric Depression Scale; SCB = Screen for Caregiver Burden; CDR = Clinical Dementia Rating; MMSE = Mini-Mental State Examination

Table 4: Methodological characteristics and quality ratings of included intervention papers

Study	Methodology	Source of carer recruitment	Primary outcome**	N	Validity criteria				
					1	2	3	4	5
Mitchell *et al.* (2001)	Before and after study	Acute care hospital, Canada	DCS	15	X	X	✓	✓	X
Sampson *et al*. (2011)	Randomised controlled trial	Acute hospital, UK	DCS and DSI	33	✓	X	✓	✓	N/A
Stirling *et al*. (2012)	Pilot randomised controlled trial	Dementia service providers and self-identified, Australia	MCSI, DCS and CPS	31	✓	X	✓	✓	N/A

***Higher quality papers are in bold**

**DCS = Decisional Conflict Scale; DSI = Decision Satisfaction Inventory; MCSI = Modified Caregiver Strain Index; CPS = Control Preference Scale

2.2.2 Barriers to decision-making

I identified four categories of barriers to decision-making. These were: 1) the emotional impact on family carers; 2) role transitions and perceptions; 3) care recipient factors and, 4) healthcare professionals, the healthcare system and access to information and I will discuss these below.

2.2.2.1 Emotional impact of decision-making on family carers

Many carers struggled to decide whether to move their relative into a care home and experienced anguish and guilt during this process (Butcher *et al.*, 2001). Two studies asked focus groups of family carers making decisions for people with dementia which decisions were the most difficult, and in both, deciding about long-term placement was identified. The first interviewed family carers of American nursing home residents with severe dementia. Many carers reported that the decision was against the care recipient's wishes, and signalled a major carer role transition. They felt a responsibility and desire to honour the care recipient's previously expressed wishes and preferences. The reluctance to move the person with dementia was weighed against the longer term benefits such as a safer environment and better care (Elliott *et al.*, 2009). In the second study, Livingston *et al.* (2010) used focus groups of British family carers to identify what were the most challenging proxy decisions, and then explored these in more depth in individual interviews. Carers discussed the responsibility of making a decision for another adult, denial, resistance by the person with memory problems, and barriers to accessing services. In many cases, the journey toward a decision was directed by a mixture of fatigue and a lack of obvious or available alternatives. Although carers often knew that the person with dementia never wanted to live in a care home, as circumstances changed they often felt compelled to act against this knowledge. Most families decided to keep someone at home as long as possible. The sense of guilt and failure seems to be particularly distressing for people obliged to cope alone.

There are also cultural issues that impact on carers' emotional strain when deciding about future place of care. Two studies interviewed Asian family carers who had recently placed a relative in a nursing home. Kwon and Tae (2012) interviewed 16 Korean adult child carers individually. Some described feeling this decision was "treachery". They struggled to find necessary information and gain family consensus. In the second study, Chang *et al.* (2011) individually interviewed 30 family carers in China, all of whom described high levels of decisional conflict when trying to balance their own needs with those of their relative. Placement was perceived to violate Chinese filial piety and as abandonment by some. Distress continued after placement, often compounded by concerns about nursing home quality, and care received. Chang and Schneider (2010) explored decision-making of family carers in China around placement and found, similarly to the higher quality study described above, that they experienced ambivalence, uncertainty, indecision and distress. It was often a whole family decision but this could make consensus harder. Disturbing the family's quality of life was often a primary reason for placement of the person with dementia, especially for carers with children in the same household.

Caldwell *et al.* (2014) compared carers from Chinese and English-speaking backgrounds. The decision-making process was similar for both but there was more of a sense of duty and need for culturally specific facilities for the Chinese carers. For Chinese carers, reluctance to decide on nursing home placement was associated with feelings of children failing in their duty, concerns that parents would think they were being abandoned, family disagreement, or not finding a suitable Chinese facility. In contrast, for carers with an English-speaking background, the attachment of the person with dementia to the family home was considered particularly important. Differing past experiences in each group led some to have fearful expectations of nursing homes and consideration of alternatives such as employing a full time maid by the Chinese group. Chinese carers had additional considerations in their choice of facility, mainly language and food, but having a facility close by to family was a stronger consideration for carers with an English-speaking background.

2.2.2.2 Role transitions and perceptions

The difficulties of role change experienced by dementia family carers were cited as a barrier by some. Cairns (2012) interviewed five family carers in the UK individually to explore unconscious processes that might contribute to placement decisions. Carers report a shift in the dynamic to a "mother/child" relationship. By contrast, once they had decided to place their relative, they often felt expected to relinquish their caregiver role because friends and relatives felt the carer/person with dementia relationship to be over. They struggled to know when it was the "right" time to place their relative. Heinrich *et al.* (2003) interviewed 20 female Canadian carers. They also described difficulty knowing when to seek care home placement due to the dementia being unpredictable and waiting lists of institutions. Many believed that they as women were responsible for caring; they worried about the perceptions of others and wanted to show that they had tried everything before seeking help.

2.2.2.3 Care recipient factors

Following interviews with family carers who had considered placement of their relative during the past year, Ducharme *et al.* (2012) concluded that the person with dementia was sometimes included in decision-making, and often those who were included were reluctant to move to a care home. This frequently led to the carer either delaying deciding or excluding the person with dementia from decision-making.

Two studies asked dementia carers about the process of deciding to access care and treatment for dementia, in the Netherlands (Wolfs *et al.*, 2012) and the UK (Livingston *et al.*, 2010). The Dutch dementia carers described this process as often emotional rather than rational and influenced by carers' personal preferences. In both studies, the person with dementia's refusal and denial, and consequent fears of causing anger or upset, were experienced as a major barrier to accessing care in a continuously changing process as dementia progressed.

Tyrell *et al.* (2006) interviewed 21 people with dementia and their primary carers in France about recently made decisions (to accept home services, a day centre, or residential care). Five aspects of decision-making were explored: information received; being listened to; expression of opinion; time allowed to reflect on decision; and possibility of changing one's mind. Carers tended to be more satisfied than patients on most criteria and many patients felt they had not been listened to sufficiently with limited freedom to participate in decision-making.

Finally, the severity of a person with dementias illness affected carers' end of life care decisions. Potkins *et al.* (2000) found that carers of people with more severe dementia were less likely to want intravenous antibiotics for life threatening infection but equally likely to want oral antibiotics, resuscitation following cardiac arrest and intravenous fluids for severe dehydration.

2.2.2.4 Healthcare professionals, the healthcare system and access to information

Information was crucial to making decisions, but after diagnosis the quality, quantity, and timing of information about dementia provided by professional services was sometimes considered unhelpful and a barrier to decision-making (Livingston *et al.*, 2010). Carers experienced feelings of guilt and distress having decided to move their relative into a care home; these were exacerbated by a perceived lack of support (Butcher *et al.*, 2001). An attitude questionnaire survey completed with clinicians and carers found clinicians valued less 'active' treatment approaches than carers when deciding how to treat potentially fatal events in end-stage dementia patients; carers valued patients' wishes, their best interests and dying with dignity more than professionals (Coetzee *et al.*, 2003).

Chrisp *et al.* (2012); Chrisp *et al.* (2013) identified influences on carers' decision to contact services to seek a dementia diagnosis and services. Similarly to Livingston *et al.* (2010), they found that this was often resisted by the person with dementia and thus

often happened when necessitated by a crisis. In a study based in the USA, 28 family carers currently considering a proxy-decision were interviewed. Six carers felt that decisions were not made but dictated by the dementia illness. These carers were less likely to make decisions until the situation was intolerable, suggesting that a more active decision-making style that perceived the situation as more within their locus of control, might help prevent decisions being taken in crisis situations. Carers report a lack of information necessary to inform their decision-making (Wackerbarth, 1999).

The healthcare system itself can also impact on carers' decision-making. In a Canadian ethnographic study, St-Amant *et al.* (2012) explored proxy decision-making by dementia family carers for people receiving homecare through face-to face interviews and participant observations with clients, family carers, and home care providers (*n* = 52). They found that the home care system, at times, imposed untimely decisions. Placement was dictated by availability rather than the person's needs and excluded some family from decision-making by requiring individual rather than collective decisions. Carers interviewed by Caldwell *et al.* (2014) anticipated a long wait for an available care home place and timed their applications accordingly.

Kraijo *et al.* (2015) interviewed 14 Dutch spouses of people with dementia after the decision to place their partner in a nursing home was made to see if they felt the admission took place at the right time. They refer to a decision-making process which starts with placing relatives on the waitlist, followed by a second decision when a place becomes available. This second decision is often taken under pressure from the care home and carers were concerned that an available place may not arise again for some time. Spouses stated that they could have cared for their relative longer at home if they had been given more time and space to make this latter decision.

Walker and Dewar (2001) interviewed UK carers about their involvement in decisions about hospital care of people with dementia, including discharge planning. Carers often felt healthcare professionals did not involve them sufficiently in decisions and were

unable to raise and discuss issues that concerned them. Barriers to involvement included hospital system processes, such as lack of resources and nature of the time pressured hospital environment and a poor relationship with nursing staff.

2.2.3 Facilitators to decision-making

I identified four categories of facilitators to decision-making. These were: 1) severity of dementia and a decision specific approach; 2) whole family shared decision; 3) involving the person with dementia and, 4) role and support of healthcare professionals and I will discuss these below.

2.2.3.1 Severity of dementia / decision specific approach

Two studies described the extent to which carers involved people with dementia in decision-making. In a small study that interviewed and observed Norwegian carers, individuals with moderate dementia were still actively involved in decision-making, especially decisions about daily activities rather than more complex decisions (Smebye *et al.*, 2012).

Samsi and Manthorpe (2013) interviewed 12 people from the UK with dementia and their carers four times in a year about everyday decision-making. Carers adopted a decision-specific approach and as dementia advanced there was a move from shared to "substitute" decision-making. Carers described using strategies to keep relatives involved such as taking responsibility for smaller everyday decisions thus allowing the person with dementia to "save" their decision-making capacities for bigger, more important decisions such as healthcare decisions.

2.2.3.2 Whole family shared decision

Carers generally found it helpful to hear the perspectives of other members of the family or professionals when making decisions on behalf of the person with dementia.

This “gave permission,” alleviated guilt and re-conceptualized care homes as providing safety, either for the carer or the person with dementia (Livingston *et al.*, 2010). Family, friends and neighbours often helped the family carer decide whether the present living environment met the person’s needs (Ducharme *et al.*, 2012). The more family support carers had during the decision-making process, the better their decision-making experiences (Kwak *et al.*, 2016). Once the decision had been made, many carers sought reassurance from others about their decision (Butcher *et al.*, 2001).

Carers’ tolerance of situations was important, with spousal carers tolerating more difficulties than adult children before resorting to a care home. This difference may be explained by the acknowledgement that spousal carers have a lot to lose financially, socially and emotionally once their relative is placed in a care home. Additionally adult child carers often have more conflicting obligations such as work and their own families which may make providing care at home more difficult (Wackerbarth, 1999). Carers reported emotional distress after the decision and sought support for their decisions from other family members and friends (Kwon and Tae, 2012).

2.2.3.3 Involving the person with dementia

Two studies investigated the extent to which people with dementia were, or would be likely to be involved in decision-making. In an American study, Sugarman *et al.* (2001) examined proxy decision-making for participation in clinical research. While carers aimed to act in the “best interest” of the person with dementia, carers are in a position to readily veto the patient’s decision if they did not agree with it. Decisions with more serious perceived consequences were less likely to be shared. Hirschman *et al.* (2005) asked 102 dementia family carers in the USA about a hypothetical treatment decision to take an Alzheimer’s disease slowing medication. Carers of people with mild or moderate dementia, with over 12 year’s education, not residing in a nursing home and who were their spouse, were more likely to involve the person with dementia in the decision. Sixty-two percent of carers said any disagreement would be resolved in

favour of the care recipient's wishes, the rest, in favour of what the family wanted for the person with dementia. Female carers were more likely to say they would resolve a disagreement in favour of their relative's wishes.

In an Israeli study, Landau *et al.* (2011) asked 94 carers who would decide about the use of a Global Positioning System (GPS) tracking device. The spouse, the next most involved family carer and the person with dementia were most commonly ranked as the most involved in the decision (first, second, and third respectively). Karlawish *et al.* (2002) asked 74 American carers about the degree to which care recipients with dementia participated in medical decisions. In most cases the carers made the final decisions (64%), a quarter reported an equal role, and a small number (8%) reported that the care recipient made the final decisions. Patients with mild dementia were, unsurprisingly, most likely to be involved in medical decisions.

Livingston *et al.* (2010) found that carers recognised the importance of making decisions about wills and power of attorney when the person with dementia retained capacity, however, sometimes only with hindsight. They were helped by knowing the person's previous wishes when making decisions, as well as experiences with other people they had known with dementia or another illness.

2.2.3.4 Role and support of healthcare professionals

Healthcare professionals can effectively facilitate the decision-making process. Collaborating with staff helped carers decide when to place their relative into a care home (Heinrich *et al.*, 2003) and where carers felt involved in decision-making, this was facilitated by a trusted healthcare professional who consulted them and advocated effectively (Walker and Dewar, 2001). Similarly, Kwak *et al.* (2016) found that when carers of people with dementia trusted the clinician they felt more informed about their values and more certain about their decisions regarding end of life care.

Torke *et al.* (2013) asked a focus group of USA carers about decision-making around cancer screening for people with dementia. Carers felt that the clinicians raising the discussion and being expert and knowledgeable helped them with the decision-making process. Carers' decision-making was based on negotiating a trade-off between quality and duration of life, and reducing burdens such as the number of tests or investigations.

Table 5: Summary of triggers, barriers and facilitators to decision-making

Triggers	Identified by
Deterioration in person with dementia	Butcher *et al*., 2001; Ducharme *et al*., 2012; Caldwell *et al*., 2014; Stephan *et al*., 2015
Carer unable to cope and care / deterioration in carer health	Cohen *et al*., 1993; Caron *et al*., 2006; Ducharme *et al.,*2012; Caldwell *et al*., 2014; Stephan *et al*., 2015
Change in living environment	Caron *et al*., 2006
Person with dementias ability to make decisions	Caron *et al*., 2006
Anticipation of long waiting lists for nursing home placement	Caldwell *et al*., 2014
Barriers	**Identified by**
Desire to honour person with dementias wishes	Elliott *et al*., 2009
Emotional impact; anguish, burden, guilt	Butcher *et al*., 2001; Livingston *et al*., 2010
Resistance from person with dementia	Livingston *et al*., 2010; Chrisp *et al*., 2012; Wolfs *et al*., 2012; Chrisp *et al*., 2013
Barriers to accessing services / lack of support / information	Wackerbarth, 1999; Butcher *et al*., 2001; Livingston *et al*., 2010
Cultural treachery and distress	Chang and Schneider, 2010; Chang *et al*., 2011; Kwon and Tae, 2012; Caldwell *et al*., 2014
Role change to 'mother / child'	Cairns, 2012
Knowing when the 'right' time to make the decision	Heinrich *et al*., 2003; Kraijo *et al*., 2015
Unpredictable nature of dementia	Heinrich *et al*., 2003; Chrisp *et al*., 2013
Preconceived responsibilities	Heinrich *et al*., 2003
Managing the inclusion of the person with dementia	Ducharme *et al.,* 2012
Severe dementia	Potkins *et al*., 2000
Person with dementia not feeling involved in decision	Tyrell *et al*., 2006
Discrepancies between carer and healthcare professionals	Coetzee *et al*., 2003; Mamier *et al*., 2014
The healthcare system	Walker and Dewar, 2001; St-Amant *et al*., 2012
Inclusion by healthcare professionals	Walker and Dewar, 2001
Facilitators	**Identified by**
Family and healthcare professionals' perspectives	Livingston *et al*., 2010; Ducharme *et al*., 2012
Support from others once decision made	Butcher *et al*., 2001
Relationship to person with dementia	Wackerbarth, 1999
Adapting caring role following a decision	Kwon and Tae, 2012
Collaborating with healthcare professionals	Walker and Dewar, 2001; Heinrich *et al*., 2003; Torke *et al.,* 2013
Mild to moderate dementia severity	Smebye *et al*., 2012
Decision specific approach	Sugarman *et al*., 2001; Samsi and Manthorpe, 2013
Wishes of the person with dementia	Hirschman *et al.,* 2005
Level of involvement	Landau *et al*., 2011
Shared decision-making	Karlawish *et al*., 2002; Hirschman *et al*., 2005; Samsi and Manthorpe, 2013; Span *et al*., 2015; Kwak *et al*., 2016
Trust of healthcare professionals	Kwak *et al*., 2016

2.2.4 Intervention studies

Four studies (Stirling *et al.*, 2012; Sampson *et al.*, 2011; Mitchell *et al.*, 2001; Span *et al.*, 2015) described interventions that sought to facilitate proxy decision-making. Two, higher quality studies, were pilot Randomised Controlled Trials (RCT). In the first, Stirling *et al.* (2012) used a decision-making aid for dementia family carers deciding whether to use community services, particularly respite care in Australia. 31 carers were randomly assigned to either receive the GOLD (Guiding Options for Living with Dementia) book decision aid or no additional support. Outcomes were measured at baseline, two and 12 weeks. As this was a pilot study, there were, as expected, no significant between group differences at any time point. However, there was a non-significant trend for those in the intervention group to report less carer burden (the study primary outcome), decisional conflict (measured using the Decisional Conflict Scale) and increased knowledge of dementia at 12 weeks. During the qualitative data collection, most carers reported finding the decision aid useful. In the second RCT, Sampson *et al.* (2011) piloted a palliative care assessment and Advanced Care Planning (ACP) discussion intervention with UK carers of hospitalized people with severe dementia. Participants were randomly assigned to the intervention (ACP) or usual care. Decisional conflict was high at hospital admission in both groups and in the carers receiving the intervention this increased at each time point. The authors reported that although discussions around the completion of Advanced Care Plans with carers were well received, many were unwilling to make decisions about hypothetical future scenarios and few carers' formalized decisions made, despite intensive healthcare professional support.

A third, lower quality intervention study, was a single group study evaluating the use of a decision aid (Making Choices: long-term tube feeding placement in elderly patients) for long-term feeding in people with dementia in a Canadian hospital (Mitchell *et al.*, 2001). Fifteen carers, who were deciding about whether a percutaneous endoscopic gastrostomy (PEG) tube should be inserted, were given an audio booklet decision aid.

After using the decision aid, carers' knowledge relevant to the decision was significantly increased and their decisional conflict reduced. No carers changed their decision after using the aid but they reported feeling more comfortable with their decision, finding the decision aid highly acceptable, helpful and they were prepared to recommend it to others.

Finally, Span *et al.* (2015) developed the DecideGuide, an interactive web tool for facilitating shared decision-making in dementia-care networks. The DecideGuide provides an online communication tool to be used by the person with dementia, their family carer and case managers for eight dementia-related life domains. All members of the care networks were given the online resource for five months. The 12 carers who participated were qualitatively interviewed and felt it helped to clarify thoughts and improved awareness of the steps of decision-making about various care scenarios. They also felt more involved in decision-making however some older participants using the electronic resource struggled with using the guide on a tablet device.

2.3 Discussion

2.3.1 Main findings

The decision to access services for diagnosis, care and treatment of dementia was the healthcare proxy decision most frequently studied. Resistance from the care recipient was a frequent barrier to this, which could mean help seeking was delayed until a crisis occurred.

Proxy decisions about place of care have been investigated in numerous studies. These decisions were often initiated by the person with dementia or carers deteriorating health, were nonlinear in nature and were often started and stopped several times before actual placement. Carers felt a responsibility to honour the person with dementia's previous wishes but care recipients, who were involved in the decision, presented barriers by mostly resisting this and were often consequently excluded from

decision-making. As the caring situation changed, moving to long-term care often felt like the only choice and carers felt burdened and guilty; Asian carers reported particular distress as moving to a care home conflicted with traditional cultural expectations.

End of life decisions, including those around resuscitation and artificial nutrition, were particularly difficult. Carers often felt excluded from decisions made in hospital and those who felt unsupported by professionals found decision-making more difficult. Collaboration with trusted, informed healthcare professionals facilitated the decision-making process for carers as did consulting with other family members in order to seek reassurance following a decision.

A small number of decision-specific manualised aids have been developed. While results for those supporting decisions about respite and percutaneous endoscopic gastrostomy (PEG) tube feeding have shown promising results in pilot trials, no intervention has yet been shown to significantly reduce decisional conflict or carer burden, increase knowledge or be acceptable for carers in randomised controlled trials. As expected, the two pilot RCT intervention studies were underpowered to provide statistically significant results. In the second, the intervention to assist with decisions around advanced care planning increased decisional conflict, perhaps because carers were being asked to consider decisions they were not actively making.

Resources for carers making proxy decisions need to be culturally specific (Kwon and Tae, 2012) and inclusive of a wider family group where appropriate. They should consider when carers need decisional support. Providing information about advanced care planning increased decisional conflict, perhaps because it was delivered at a time when they were not being asked to make the decisions discussed but it was too late to involve the people with dementia in those decisions. Further investigation is required in order to establish at what point these interventions should be delivered to people with dementia. Feedback from the delivery of the START manualised intervention

(Sommerlad *et al.*, 2014) suggested that providing carers with strategies and resources early in the dementia illness helped by equipping them with skills they could then implement when they needed to.

2.4 Limitations

Most studies asked convenience or purposive samples of family carers about decision-making and inevitably, those that volunteer to discuss their experiences may differ systematically from carers who did not. For example, they might have found the experience particularly distressing, or have been relatively better informed about services and how to access information. Proxy decision-making in dementia may sometimes be a fairly straightforward process; if health professionals and relatives agree that the decision is in line with earlier wishes and culture and the person with dementia does not or cannot object. At other times it is complex, affected by factors including dementia type and severity, physical health, personality and previous experiences. Additionally, factors such as financial resources of the person with dementia, health, knowledge, experience and other demands on the family carer, family dynamics, the approach, skills and experiences of the professionals involved, as well as the specific qualities and context of the decision to be made also impact the decision. Qualitative studies can try to capture this complexity but inevitably some of the context of decisions reported in studies is lost, especially as the perspective of only one family member involved in the decision is sought, and this may be some time after the event. In studies exploring hypothetical decisions, it is unclear how the decisions carers think and report they would make, reflect what they would actually do in a real situation.

2.5 Conclusions

Family carers want practical support with decision-making but often report this is not readily available from healthcare professionals. Decision-making is time sensitive;

options and opinions can change over time, usually in parallel with the advancement of the dementia disease. Carers want professionals to raise issues relating to decision-making around the time of the decision, and have demonstrated high levels of decisional conflict, emphasizing the potential benefit of decision-making support in this group. No intervention has yet been shown to significantly reduce decisional conflict in a randomised controlled trial, but results from preliminary studies suggest that family carers find manualised decision aids useful and their further development and evaluation is warranted. These could usefully focus on decisions around placement and accessing services and end of life care decisions; these have been reported in higher quality qualitative studies to be associated with conflict and distress. Being provided with information to make decisions which have not previously been considered may increase feelings of conflict, suggesting these aids should be carefully targeted.

Chapter 3 The DECIDE study

3.1 Research aims and objectives

The project's primary aim is to develop and test in a randomised controlled trial (RCT) the feasibility and acceptability of the DECIDE manual, a decision aid to enable family carers to make decisions about the future place of residence of people with dementia.

Phase one objectives

1. To identify important components of the DECIDE manual through qualitative semi-structured interviews with carers and individuals with dementia.
2. To prepare a first draft of the DECIDE manual and consult clinicians working with people with dementia and their family carers through focus groups.
3. To finalise the DECIDE manual for testing in phase two incorporating existing guidelines and evidence.

Phase two objectives

1. To test my primary hypothesis that family carers who receive the DECIDE manual intervention will find it relevant and useful.
2. To evaluate trial recruitment and retention in preparation for a full, pragmatic trial of the intervention.
3. To inform sample size for a future, full RCT to test whether family carers who receive the DECIDE manual intervention will report lower scores on the Decisional Conflict Scale total score and the Decisional Conflict Scale informed sub-scale when compared to family carers in the treatment as usual group 10 weeks post baseline.

4. To explore through qualitative interviews what components of the intervention were useful and whether and how it helped carers make decisions and to elicit their views about how the manual might be implemented into clinical practice.

Chapter 4 Developing the theory

In this chapter, I will describe the main conceptual models on which decision aids have been based, and justify my selection of the Ottawa Decision Support Framework (ODSF) (O'Connor *et al.*, 1998) and the International Patient Decision Aids Standards (IPDAS) (Elwyn *et al.*, 2006) criteria as a theoretical basis for the development and evaluation of the DECIDE manual.

An analysis of 50 randomised controlled trials of decision aids found that only a third explained the contribution of decision-making theories or models in the design, development and evaluation process (Durand *et al.*, 2008). There are numerous decision-making theories that describe, explain and predict how people make complex decisions and circumstances that lead to decisions with poor outcomes. Building decision aids around a particular theory can provide a framework to test its effectiveness systematically.

4.1 The Decision Analytic Method

This method models a decision-making process by giving a cost and a probability of occurrence to each potential option within a decision then combining these to generate the expected cost of each course of action (Howard and Matheson, 1984). The 'decision tree' is the direct application of this method (Magee, 1964). In the context of the DECIDE manual, this theory would require participants to specify the utility of each option about future place of care on a numerical scale (giving a cost to these), that would be multiplied by the outcome probabilities of each option to identify the option with the highest subjective utility. As there is limited, often conflicting, evidence about dementia outcomes for people who do and do not enter care homes, due both to a lack of research and the unpredictable nature of the disease, this approach would not be well suited to a dementia decision aid. Also, this model takes limited account of contextual factors, which, as my systematic review in Chapter two

highlighted, are important for carers of people with dementia when making placement decisions.

4.2 The Interprofessional Shared Decision-Making (IP-SDM) Model

This model broadens the doctor-patient dyad of decision-making to include family members and a 'decision coach' who is a healthcare professional. It describes three levels; the individual level (the micro level), the healthcare teams within an organisation level (the meso level) and the broader policies and social contexts level (the macro level). At the individual level the patient, healthcare team and family members work through a structured process to make an informed decision; at the meso level, there is an individual within a healthcare team who initiates the shared decision-making process and a decision coach who is non-directive and provides support to all involved in the decision-making process; finally the macro level assumes that an interprofessional approach to shared decision-making will not occur independently of influence from the healthcare system. This is a relatively new theory developed and currently there are no publications of decision aids based on this model. I did not use this as my model as it is less evidenced than my selected model, but learnt from their description of the role of 'decision coach' when considering the role taken by the healthcare professional completing the DECIDE manual with carers.

A number of trials using decision aids have included decision coaching. Decision coaching is 'the process by which a supportive and knowledgeable health professional provides a patient with individualized, nondirective guidance to meet decision-making needs in preparation for consultation with the person ultimately responsible for sharing the decision with the patient' (Stacey *et al.*, 2012). Guidance and coaching seek to improve communication, provide support and avoid inconsistencies in how information is presented (Stacey *et al.*, 2012).

4.3 The Ottawa Decision Support Framework (ODSF)

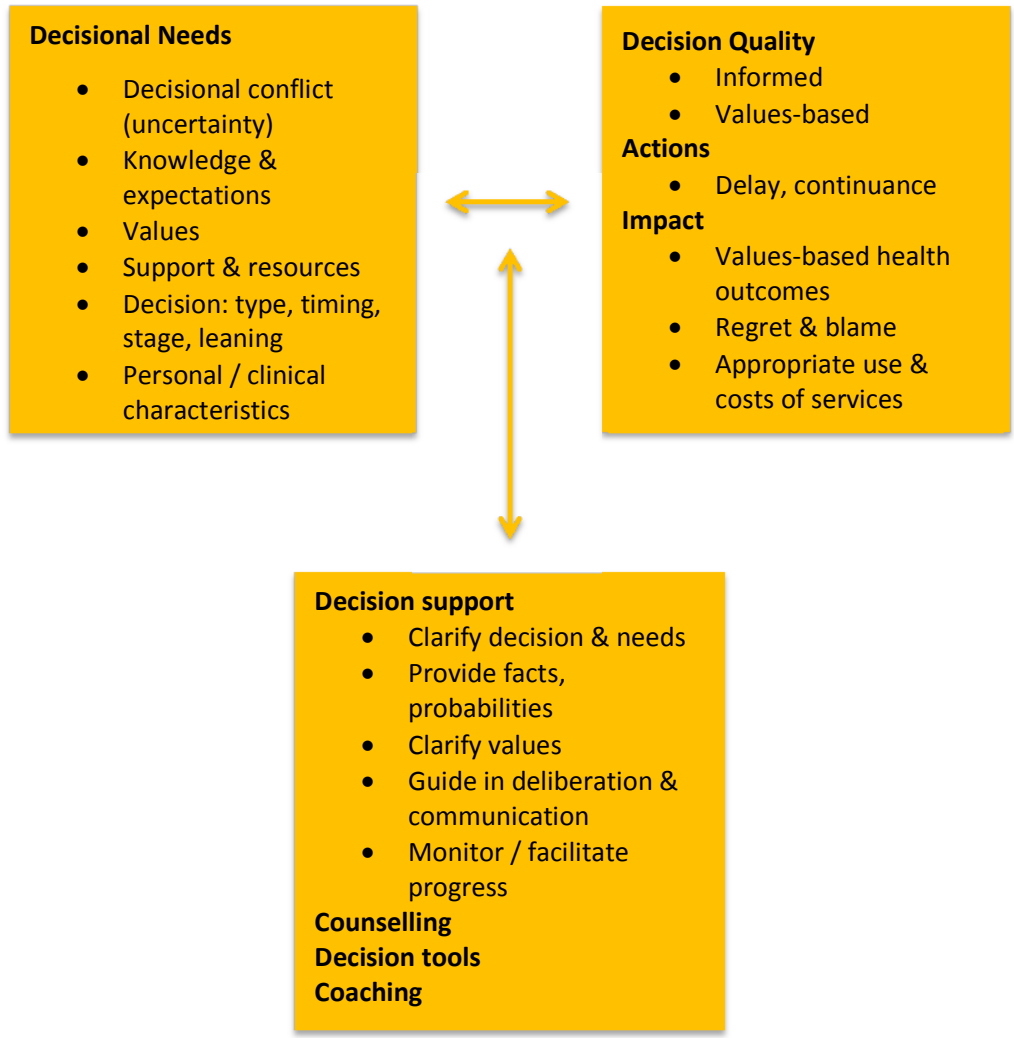
This is 'An evidence-based, practical theory for guiding patients making health or social decisions' (O'Connor *et al.*, 1998). It was created to guide the development and evaluation of interventions to facilitate shared decision-making between patients and healthcare professionals (Légaré *et al.*, 2006). The Ottawa Decision Support Framework has informed the development of numerous patient decision aids (O'Connor *et al.*, 2002; Murray *et al.*, 2004; Durand *et al.*, 2008). When compared to usual care or simpler information leaflets, decision support interventions developed using this framework increased knowledge, patients had more realistic expectations and reduced decisional conflict. Such interventions increased the number of people who were active in decision-making, reduced the number of people who remained undecided and resulted in greater agreement between individual's values and choice (Légaré *et al.*, 2006).

The Ottawa Decision Support Framework draws on a number of decision-making theories including the 'conflict theory model of decision-making' and the 'expectancy value model'. The 'conflict theory model of decision-making' assumes that the decision-making process is stressful and creates uncertainty and conflict within the choice situation. This is managed by the decision maker looking for and evaluating the information available and all alternatives. The 'expectancy value model' states that when people are asked to choose between two or more options with significant harms and benefits, they are more likely to choose the option with the highest expected values and success. The Ottawa Decision Support Framework identifies modifiable factors that can be targeted for specific decision-support interventions to reduce decisional conflict. It takes account of decision needs, decision quality and decision support (see Figure 4). An 'effective decision' in this instance will be a decision whereby there is reduction in decisional conflict for carers.

The Ottawa Decision Support Framework model fits well with the decision-making situation the DECIDE manual targets. Clarifying values with carers, increasing feelings of support and reducing uncertainty by making them more informed would, from the evidence I identified in my systematic review, appear to be rational strategies for reducing carer decisional conflict.

The Ottawa Decision Support Framework identifies decisional conflict as a key element in the decision-making process. The Decisional Conflict Scale was developed from the framework and can be used to evaluate the quality of a decision about care and if the decision is informed and consistent with the individual's values. In a recent systematic review, 58 randomised controlled trials used the Decisional Conflict Scale as an outcome, and I will use it in this trial as a secondary outcome.

Figure 4: The Ottawa Decision Support Framework (ODSF)
(O'Connor *et al.*, 1998)



4.4 International Patient Decision Aid Standards (IPDAS)

Due to the increasing number of decision aids available, a need for quality criteria was identified. The International Patient Decision Aid Standards (IPDAS) collaboration is an international group of researchers, practitioners and stakeholders established in 2003 to enhance the quality and effectiveness of patient decision aids by establishing a

shared evidence-informed framework with a set of criteria for improving their content, development, implementation, and evaluation (Elwyn *et al.*, 2006). The IPDAS group reached agreement on criteria for judging 'the things that you would need to observe in order to say that after using a patient decision aid, the way the decision was made was good and that the choice that was made was good' (Stacey *et al.*, 2014). The full criteria checklist covers domains including content, the development process and effectiveness of the decision aid (see Appendix 2 for criteria checklist). The checklist authors acknowledge that the number of criteria is high and many may be difficult to attain; they do not intend the criteria to be prescriptive and it was not designed to provide precise, quantitative assessments so that judgements about quality of a decision aid can be made (Elwyn *et al.*, 2006; Elwyn *et al.*, 2009). Therefore, the IPDAS collaboration developed an instrument to measure the quality of development process and design elements of decision support technologies, known as the IPDASi (v4.0) (Elwyn *et al.*, 2009; Joseph-Williams *et al.*, 2014). The 44-items that the tool consists of are assigned into three categories; the first category 'Qualifying criteria' includes six items that if all met, define that tool as a patient decision aid. The second category of 10 items, the 'Certification criteria', relate to the quality of the evidence synthesis process, disclosure of funding source and balanced presentation of options. Finally, the third category 'Quality criteria' includes 28 items that would improve the experience of using the decision aid but the absence of them would not be expected to influence the individual's decision in a negative way (Joseph-Williams *et al.*, 2014). A recent study examined the feasibility of the use of such an instrument with an existing set of decision support interventions (Durand *et al.*, 2015). It was concluded that whilst a minimum criteria was feasible, further development of this is needed for interventions concerning screening and diagnostic tests and for those to be used within a clinical encounter. There was also considerable inter-rater variation whilst assessing the decision interventions using the IPDASi, highlighting the training needs for the use of such a tool. The collaboration recommends consideration of these standards in

development of future decision aids whilst recognising there is still development work needed (Durand *et al.*, 2015).

4.5 Summary

For the reasons cited above, I based the DECIDE manual on the Ottawa Decision Support Framework. I adhered, as far as practicable, to the International Patient Decision Aid Standards and I report the extent of adherence of the final DECIDE manual to these standards and reasons for deviation in Chapter eleven and Appendix 29.

The DECIDE manual will be a guided decision aid that participants will read through and complete with the support of a 'decision coach'. In the feasibility trial, I will take this role. If the manual were to be used in clinical practice this role would be undertaken by a healthcare professional therefore I have consulted with healthcare professionals throughout its development.

Chapter 5 DECIDE study Phase one

This chapter details the initial stage of the DECIDE manual development in which I qualitatively interviewed people with dementia and their family carers. A paper from this work was published in BMC Geriatrics (Lord *et al.*, 2016) (Appendix 3).

5.1 Ethics committee approval

I obtained research ethics approval for phase one of the DECIDE study from National Research Ethics Service Committee London – Bloomsbury (January 2014; REC Reference: 14/LO/0012) (Appendix 4). Local NHS Research and Development (R&D) approvals were obtained from all study sites; Camden and Islington NHS Foundation trust and Barnet, Enfield and Haringey Mental Health Trust (Appendix 5). All participants gave written, informed consent.

5.2 Recruitment and sampling

Recruitment took place between February 2014 and July 2014. I recruited family carers and people with a clinical diagnosis of Mild Cognitive Impairment (MCI) or dementia from three memory clinics: Camden Memory Service, Islington Memory Assessment and Treatment Service and Haringey Memory Service. Clinicians working within the memory clinics identified people with Mild Cognitive Impairment (MCI) or dementia and their family carers and gave them both a copy of the study information sheet (Appendix 6 for patient information sheet and Appendix 7 for carer information sheet). In order to aid recruitment, posters advertising the study were placed in participating memory clinics (see Appendix 8). I did not include potential participants who lacked capacity to decide whether to take part, as defined and measured by the Mental Capacity Act (2005). If the clinicians or researchers at any point judged an individual lacked capacity, they were excluded from participation in the study.

In order to encompass the range of views and maximise the validity of the findings I sought to interview a demographically diverse range of people with dementia and carers who were currently in the process of making a decision about, or had recently made the decision about, future place of care or residence. We therefore recruited purposively to include the following: individuals of either sex, encompassing a range of age groups, ethnicities, spousal and child carers and dementia severity.

5.2.1 Participant inclusion/exclusion criteria

Inclusion criteria for family carers were:

- Current, unpaid, main informal carer (e.g. a family member or friend in regular contact who is either next of kin or a 'key decision maker').
- English language skills sufficient to participate in interviews. Whilst it is acknowledged that the ideal would be to use the first language of all potential participants, unfortunately there were not funds to provide interpreters.

Exclusion criteria for family carers were:

- Carers under the age of eighteen.
- Carers where there are clinical concerns that may preclude them from being approached, such as severe physical or mental illness.
- Lack of capacity to give informed consent and complete the interview.

Inclusion criteria for people with memory problems were:

- Individuals with a clinical diagnosis from the memory clinics of either Mild Cognitive Impairment (MCI) or dementia.
- English language skills sufficient to participate in interviews.

Exclusion criteria for people with memory problems were:

- Concerns that may preclude them from being approached, such as severe physical or mental illness.
- Lack of capacity to give informed consent and complete the interview.

Recruitment ceased when it was judged that data saturation was reached; this is when the inclusion of additional interviews does not significantly add to the knowledge that has been gained (Glaser and Strauss, 1967).

5.3 Procedure

Clinicians provided contact details of potential participants who expressed an interest in knowing more about the study and agreed to be contacted. Following this, I telephoned potential participants to discuss the study, answer any further questions and if they were willing to participate, sent a further copy of the information sheet (where requested). At least three days after this telephone contact and sending this information, I arranged a meeting with the potential participant to elicit informed consent (see Appendix 9 and 10 for patient and carer consent forms) and complete the interview. I conducted all semi-structured interviews in a location convenient to the participant, either in their own home or in appropriate university buildings. All participants were offered the opportunity to be interviewed either alone or, in the case of a person with dementia and carer dyads, to be interviewed together.

The semi-structured interviews followed a topic guide I developed from the CHOICE study findings regarding barriers and facilitators to decision-making about change in place of care as reported by family members of people with dementia (Livingston *et al.*, 2010) (see Appendix 11 for patient topic guide and Appendix 12 for carer topic guide). I also consulted clinicians from memory clinics (Old Age Psychiatrists and Clinical Psychologists) and dementia researchers regarding any further relevant topics.

5.3.1 Semi-structured interview topic guide

I asked people with dementia and family carers about current living arrangements; whether they had any concerns about where the person with dementia lives (and prompted them to consider loneliness, distance from family, safety and the care available). I explored any differing views within the family and between the family and the person with dementia. I also asked participants to detail the extent to which they had been involved in making decisions and if they experienced any difficulties; whether they had felt supported and by whom (with prompts about family and healthcare professionals). I asked whether they had talked to anyone about this decision and if so whether this was helpful.

I explored with participants what might help to make this decision about future place of care and whether there was any information they wished they had been given. I then prompted them by showing them two existing information resources and asking for comments and improvements to these in terms of form and content and specifically when and how they would want to use this information. I used the CHOICE factsheet entitled 'Deciding about a care home?' and the accompanying 'Resources for carers' factsheet (Appendix 13). The CHOICE factsheet is three pages in length and is a combination of advice and guidance on some of the issues carers may face when making this decision, accompanied by quotes from research participants. Topics covered include how to make the decision about a care home placement or not; what may happen after a person goes in to care and what financial help is available. The 'Resources for carers' factsheet provides a list of 18 resources such as charities and other agencies for carers which may be able to provide help and support during this process.

5.4 Analysis

All interviews were digitally audio recorded and transcribed verbatim. All identifying information was removed to preserve participants' anonymity and stored on a password protected database in accordance with the Data Protection Act (1998).

All interview participants were offered the opportunity to read, comment and make any alterations to their interview transcript, as a quality control and validation strategy. Participants can ensure that the transcript is a true record of what they intended to say or, where necessary, can elaborate or provide a more nuanced perspective. Only two participants chose to review their transcripts and they made no changes to these.

I based my analysis plan on Braun and Clarke's phases of thematic analysis: familiarisation with the data, coding, searching for, reviewing and naming themes and writing-up (Braun and Clarke, 2006). I used the qualitative research software programme Nvivo 9 to code, manage and analyse all data. I, and a second researcher, thematically coded all data independently to ensure reliability, generating a coding frame from initial interviews using a thematic content analytic approach. Disagreements between the researchers were resolved through discussion and a consensus was reached.

5.5 Results

5.5.1 Demographics (Table 6)

I interviewed 20 participants; seven with dementia, four of whom had a family carer participating and an additional nine family carers (*n*=13). One of the people with dementia and their family carer were interviewed together. All other interviews were conducted individually.

The socio-demographic characteristics of both carers and people with dementia are detailed in Table 6. One of the participants with dementia had recently moved to a care home due to family concerns about their safety and another had moved out of a care home and into their relative's home in a different part of the country. All of the other five people with dementia interviewed were currently living in their own homes. The nine carers who were interviewed without participation of their relative all had relatives with dementia who were living in their own homes and were considering their options about future place of care.

Table 6: Participant characteristics

		Carers (*n*=13)	People with dementia (*n*=7)
Sex	Male	4	5
	Female	9	2
Age (years)	Range	32 - 85	71 - 87
	Mean	59	79
Relationship to person with dementia	Spouse or partner	5	N/A*
	Child	7	N/A
	Niece / Nephew	1	N/A
Living situation	Alone	2	2
	With partner	10	1
	With other relatives	1	3
	In care home	N/A	1
Ethnicity	White British	11	6
	Asian	2	1
Current living environment	Flat / House	13	6
	Residential care home	N/A	1

*N/A = Not applicable

5.5.2 Thematic analysis

The main themes identified are detailed below.

Theme 1: Who makes the decision?

People with dementia sometimes felt, and resented the fact, that they were not supported to participate in decision-making:

> *"I feel it's rather humiliating frankly to be treated as incompetent, unable to make my own decisions really… I feel rather that I've sort of been taken over a bit and they do my thinking for me and I don't really like that very much actually" [Man with dementia living in a care home; 05]*

There were instances in which people with dementia felt that a change in their living situation was a forced decision over which they had no control or influence:

> *"Well I was, quite honestly I was forced into it…the thing is that I would like to perhaps be given some option" [referring to son moving him to a care home] [Man with dementia living in own home; 04]*

One participant did not think that the person making the decision had the right to do so:

> *"I don't really feel I've given him the rights" [referring to care home manager getting involved in decision about where to live] [Man with dementia living in a care home; 05]*

In other cases, people with dementia and their carers felt the decision-making process had been shared:

> *"Well we all sort of sat around, the three of us [person with dementia and two children] trying to find out where's the best sort of nursing home" [Woman with dementia living in own home; 08]*

Carers recognised that they were taking over decision-making and sometimes found this change of role difficult or overwhelming. They often acknowledged excluding the person with dementia from the process because they lacked insight into the problems necessitating a move:

> *"I'm doing everything that my husband was doing before" [Wife of person with dementia; 015]*

> *"My whole identity was caring for them" [Daughter of person with dementia; 06]*

> *"He doesn't want to go anywhere" [Wife of person with dementia; 015]*

None of the people with dementia or their family carers described being able to refer to advance statements or written recording of the views of the person with dementia, at a time when their dementia was less severe.

Theme 2: The wider family

Where carers were making surrogate decisions, such decision-making was often shared with or discussed with the wider family. Moves affected other family members, especially where they were moving from a home shared with their spouse to a care home, or where moves were over longer geographical distances. Sometimes family members were moving to be nearer the person with dementia, other times the person with dementia was moving nearer to their relatives. This was often a difficult decision to make as it ultimately resulted in someone having to leave their home and local area, thus impacting on their social contact outside their immediate family.

> *"The main reason really for wanting to keep her up there [north England] as opposed to bringing her down here [London] to go to a nursing home down here was because of her friends" [Daughter of person with dementia; 07]*

People with dementia and their families were concerned about isolation of the person with dementia. Sometimes carers were torn between the emotional and practical needs of the person with dementia, their own needs and other family members. One carer excluded the person with dementia to try to protect their feelings:

> *"My father went to pieces when she went into respite [mother with dementia]. This is really important info because that totally changed my view about what could happen to my mother. It made it very clear that if he remained as aware as he is, they couldn't be separated" [Daughter of father with dementia; 06]*

> *"'The big problem has occurred, as I knew it would, that I don't see anybody" [Woman with dementia living in own home; 08]*

Carers reported consulting family and friends about the decision to move their relative. Some found this helpful whilst others felt it created tension where views differed:

> *"We're both honest with each other and it's such a help, I don't feel I've got to hold back or that I'm going to upset her [when talking to another carer of a person with dementia]" [Wife of person with dementia; 012]*

> *"When I think about it I think there are areas that are still a bit taboo between us, maybe we're protecting each other" [Wife of person with dementia; 012]*

Theme 3: Familiar environment

All carers expressed a desire for the person with dementia to maintain living in their own home and caring for them there where possible as they recognised familiarity of the environment and preservation of their daily routine as important:

> *"Well I don't think either of us will move from here because we've been here so long and we like it" [Husband of person with dementia; 011]*

Proximity to local amenities, such as public transport and shops, was seen as an important factor in maintaining independence. The people with dementia valued remaining at home highly, especially as they often lacked insight or did not agree with reasons behind a move:

> *"I have suggested these things to him, that a carer might be satisfactory… well he doesn't like it... yea because I think it usurped his position" [Man with dementia living in own home; 04]*

Individuals with insight into their dementia often raised the discussion around the need for additional care or moving to a different care setting and expressed feelings of guilt around having the illness.

> *"He feels very guilty anyway... I don't want him to feel that it's [the dementia] going to blight my life" [Wife of person with dementia; 012]*

Theme 4: Safety

Safety concerns about falls or unsafe use of gas or electric kitchen devices, coupled with accessibility issues were the most commonly reported problems that triggered the decision-making process for both carers and people with dementia:

> *"I think we should be in a flat… having things on one level will help. I'm keen to be somewhere where we're not so dependent on a car. So nearer transport, nearer shops" [Wife of person with dementia; 012]*

> *"I'd like to be sort of more truthful about it you know, not try to kid myself, but there are difficulties. I mean I'd need quite a lot of help I think… the trouble is you see, nobody could be on 24 hours [when discussing carers coming to own home]. I really think I need to be monitored really" [Man with dementia living in a care home; 05]*

In some cases, the person with dementia accepted that the carer had concerns and, as they trusted the carer's view, they also accepted this as a reason to move:

"He [the carer] was very much, very keen I should get into somewhere so that I couldn't fall over" [Man with dementia living in a care home; 05]

Theme 5: Physical health

Participants discussed no longer being able to manage at home due to physical health problems. These were unrelated to the dementia but the complexity of problems made solving them difficult:

"'My brother was taking her [home] and realized there was just no way he could leave her at home, she was just in no state for that [due to pain]" [Daughter of person with dementia; 07]

"It got very tough because she couldn't get into the bath due to her knee, had to be strip washed… It's urgent because she's falling over" [Daughter of person with dementia; 06]

Participants were aware that adjustments to their current environment may enable them to stay at home longer but not all were sure how to make these adjustments and if there were services available to help:

"We don't know who to contact, we are completely lost" [Wife of person with dementia; 03]

"I still feel that I don't know all the questions to ask…I mean who gets involved, is it Social Service, who is it? And how does that begin?" [Wife of person with dementia; 012]

Theme 6: Carer health issues

Several participants, all from the spousal couples interviewed, raised concerns about the carer's health impacting on their ability to provide care in the future:

"I am concerned about [wife's] health…I do worry that we're both losing it" [Man with dementia living in own home; 013]

"That is something that worries me, if I get worse, who is going to look after him? That's my main worry" [Wife of person with dementia; 015]

"We've also got to face the fact that we both might need care" [Wife of person with dementia; 012]

Theme 7: Uncertainty about the future

A central theme throughout the interviews was the knowledge that dementia progresses but uncertainty about the specific course of the illness:

"We're coping pretty well at the moment but you know in years to come it could, you know it will probably get worse" [Husband of person with dementia; 011]

"It is one of those things that I should be thinking about more and making more plans about [wife with dementia's future living arrangements]" [Husband of person with dementia; 014]

"I want him to stay here, I want to do as much as I can but I really don't know what the future's like you know, I have no idea" [Wife of person with dementia; 015]

Theme 8: Navigating health and social care

Many participants reported being unsure which healthcare professional or agency they should or could talk to, which services they were entitled to or whether services existed:

"But we don't know who to contact, we are completely lost" [Wife of person with dementia; 03]

Some felt excluded by the inclusion criteria of memory services:

> *"If you are not on medication you are instantaneously discharged from the memory service…. So you are saying the whole service is utterly and totally determined by a pill? And it's not just that that's absurd, it's actually very upsetting, it's personally, I can't describe this feeling of exclusion" [Daughter of person with dementia; 06]*

Lack of support and planning for a crisis from healthcare professionals was highlighted:

> *"One of the problems within the whole decision-making process is firstly is it's very unsupported, but secondly there was no plan b, there was no contingency for a crisis" [Daughter of person with dementia; 06]*

Nearly all carers and people with dementia expressed concerns regarding how services and care were to be paid for both now and in the future which ultimately impacted on decisions that were made when thinking about place of care:

> *"It was a sense of this can't carry on and they shouldn't be bearing the cost of care because they don't have much savings left and the house is the asset and I don't know what's available" [Daughter of person with dementia; 06]*

> *"Well one thing which I find is that it's quite expensive, I'm paying £1000 a week' [for respite accommodation in a care home]… there's a limit to the amount I could do that" [Man with dementia living in a care home; 05]*

Previous experiences, both positive and negative, with other family members with dementia who moved to a care home, influenced carers and people with dementia interviewed. Media portrayal of care homes also impacted decisions not to use a care home:

> *"What I hear every time on the television, what I read and you know, no, no…we have been married over 50 years and I would hate to put him in a place where he's not well looked after" [Wife of person with dementia; 015]*

Theme 9: Development of a decision aid

Participants responded positively to the idea of a decision aid focused on future place of care and that it might help carers feel better to hear from others in a similar situation:

> *"It's probably useful to know that the kind of, what you are thinking yourself is actually the way it is, that's the way people think, other people, and that's comforting I think" [Daughter of person with dementia; 07]*

Theme 10: What should be included in a decision aid?

Participants wanted discussions about what services are available at home to be included in a decision aid. In addition, they sought information about changes that may occur for the person with dementia or their carers that may ultimately impact place of care decision-making:

> *"The only thing that I would like to have a bit more of is more information about what help is available at home" [Wife of person with dementia; 012]*

> *"Probably more of a discussion about the ways in which circumstances could change, how they might change for the carer who's own health or something may be deteriorating" [Husband of person with dementia; 014]*

In terms of decision-making about place of care, both people with dementia and carers highlighted the importance of knowing that a move to a care home is not the only option available and should not be the sole focus of the information given and that sufficient details of alternatives should be provided:

> *"Why is it so much about care homes? Why not have carers living in? … Most people I've come across, ok they find it difficult having a carer in their home but it's still better than being in a care home" [Daughter of person with dementia; 07]*

Information about how and where to access details about other organisations that may provide support or information about finance or care homes was seen as an important addition to a decision aid. The list of contact details of available resources for carers and people with dementia such as Age UK and the Alzheimer's Society was well received and provided information participants had not previously been given:

> *"Oh how wonderful... Oh yes, excellent, some of these I haven't heard of! [It's] quite reassuring saying where you can get information about it because I think the financial side of it must prey on a lot of people's minds" [Wife of person with dementia; 012]*

Many felt that simply the name and contact information about these organisations was not sufficient, and although these were seen as important, details about what exactly these agencies do was necessary:

> *"It doesn't tell you what the various organisations, what the resources have to offer... I think you would do better to have a very small number and describe more carefully what they do" [Husband of person with dementia; 014]*

Theme 11: How should a decision aid be delivered?

Participants discussed how the resource could be delivered and the importance of human interaction and support given the complicated nature of this decision-making process:

> *"That moment of being, feeling really supported, that's why I wonder when you talk about a resource, for me, the most important resource are humans… Sitting next to somebody filling in a form together was, I can't tell you how supportive that was" [Daughter of a person with dementia; 06]*

The added benefits of the decision aid being delivered by a professional and having the discussion about future place of care face-to-face can help to clarify views and opinions on the issues that need to be considered in decision-making:

"Talking to you has made it clear to me that my responses are very mixed" [Wife of person with dementia; 012]

Theme 12: When should a decision aid be used?

All participants were very clear that information about future place of care should not be delivered at the point of diagnosis:

"I think that will worry people a lot… they will think the worst… let the patient get used to it a little bit, let it sink in a bit you know and see what progress" [Wife of person with dementia; 015]

"I mean it can't be right at the beginning, you can't cope with it" [Wife of person with dementia; 012]

Carers felt that waiting until the dementia had progressed and also relying on the knowledge of expertise to raise the issue was important:

"Well not on diagnosis, I think you know, maybe after two or three years" [Husband of person with dementia; 011]

"That's probably a judgement of the memory clinic... a major part of the remit of the clinician in the memory clinic, you know, is to just assess how things are going I think by directly asking the question and also trying to look beyond the answers... people probably are reluctant to say 'oh it's all getting a bit much for me' and perhaps you have to draw that out of them a bit more" [Husband of person with dementia; 014]

"You don't really want to do it too early but you don't want to do it too late so I think it is a matter of judgement really" [Daughter of person with dementia; 01]

There were also specific points throughout the disease that were suggested as an appropriate trigger to then receive this information. This included the point at which

the person with dementia begins to take medication for their dementia and when discussions begin around Lasting Power of Attorney:

> *"Certainly once he went on the medication which I think made it all the more real. Once we started talking about these enduring powers of attorney" [Wife of person with dementia; 012]*

Theme 13: Views on the CHOICE factsheets

Some participants were positive in terms of the layout of the factsheets. Others felt the comments from previous participants distracted from the purpose of the factsheets, while recognising they may be reassuring to others:

> *"I like the way the print is really bold and differentiated between the statements and comments" [Wife of person with dementia; 012]*

> *"It is useful having the quotes because also they give different perspectives don't they?" [Wife of person with dementia; 012]*

> *"Perhaps at the end you could have a few comments. But to my mind they are just kind of interrupting. Yes, I don't like the way they are interspersed like that" [Daughter of person with dementia; 01]*

> *"You're certainly starting off with the right question which is a question of 'does the person with dementia need to go into a care home?" [Husband of person with dementia; 014]*

> "*Deciding about a care home' it does, 'a care home' does seem a bit bare bones and 'deciding about a beautiful place to live" [change to make more positive] [Man with dementia living in own home; 04]*

> *"Why is it [the leaflet] so much about care homes as well? Why not have carers living in?" [Daughter of person with dementia; 07]*

Others felt that they provided no new information and that third sector organisations already provided some of this information:

> *"Age UK do it [borough specific contact information] so why re-invent the wheel? Just make sure you don't overlap too much with them" [Daughter of person with dementia; 07]*

> *"The Alzheimer's Society has some literature which is quite...it's all fairly obvious but it's quite useful" [Daughter of person with dementia; 01]*

5.6 Discussion

The nature of the illness means people with dementia may have had difficulty remembering how decisions were taken. Where possible, I spoke to carer-care recipient dyads, so I could explore the process from both perspectives. Most of the people with dementia I interviewed did not feel part of decision-making about place of care. Some preferred their family to decide for them but others felt excluded and even humiliated by not being included. Carers often reported that it was not possible to involve the person with dementia in the decision due to their lack of understanding of the issues necessitating a move.

The people with dementia reported a strong desire to continue living in their own homes. Carers recognised and echoed this desire but concerns around the safety and ability of people with dementia were often such that it was not possible. The healthcare status of carers can be a crucial factor in the decision-making process. Support both from other family members and healthcare professionals was sought and valued, but consistent with other research reports, many carers found difficulty in negotiating the complicated healthcare system (Graneheim *et al.*, 2014).

None of the people interviewed drew on discussions about place of care earlier in the dementing illness or advanced statements when making their decision. Perhaps the dementia was diagnosed too late for the person to be involved in planning care, or

perhaps opportunities for discussions that might have eased the difficulty of later decision-making were missed. Carers often find planning difficult and Advanced Care Plans (ACPs) have not been widely taken up (Dening *et al.*, 2012). Decision-making for the long-term can be avoided by carers due to fear of confrontation with the care recipient and fears of this uncertain future (Sampson and Clark, 2015). Sometimes there are too many uncertainties to draw up definitive plans for the future. The carers and people with dementia I interviewed were clear that information about planning for place of care could compound distress if given at the point of diagnosis of dementia. This is useful information, but reduces the window to deliver support around making these advanced decisions.

There may be limitations of the findings due to sample size, although in a review of over 500 qualitative research projects sample sizes, the most common were 20 and 30 (Mason, 2010). I only interviewed people who had capacity, so did not include people with more severe dementia, although I did speak to relatives of people with more severe dementia. I interviewed only those able to speak English fluently; those that did not may well have viewed decisions around place of care differently. Ethnicity has been found to influence the decision to look after an individual with dementia at home with people from ethnic minorities 40% less likely to enter 24 hour care (Cooper *et al.*, 2010). Carers from ethnic minorities also report issues with filial piety and obligation (Chang and Schneider, 2010; Chang *et al.*, 2011) and that there is often a lack of culturally appropriate facilities especially in terms of language and food (Caldwell *et al.*, 2014).

The decisions about placement were often made at a point in the illness when insight into risks and abilities to stay at home were lost. Consequently, people with dementia were sometimes unable to contribute fully, or at all, to the decision, whilst carers felt overwhelmed and distressed. Participants described the decision as a balance between the importance of remaining in a familiar environment and the need to reduce unacceptable levels of risk or accidents at home. The effect on wider family and carers'

health were considered. Support from healthcare professionals was appreciated but sometimes confusing to access or provided inadequate assistance to those making this pivotal decision about place of care for people with dementia.

This data supports the need for development of an intervention to help people with dementia and their families and carers have facilitated discussions about issues of future place of care earlier in the illness, in which decisions about whether, when and where placement or alternative solutions might be needed in future could be worked through. My findings would support an interactive and individual resource, completed with a healthcare professional to allow opportunity for clarification of thoughts and a written record. Such a resource may encourage the use of family and other resources, such as third sector organisations, and signpost to these. Additionally, it would provide details of how care needs may change in the future and the impact of these on both the person with dementia and their carer, whilst also providing information on the place of care options available.

5.7 DECIDE manual: version one

Following the collection of the data from people with dementia and their carers I drafted version one of the DECIDE manual (Appendix 14). As the CHOICE factsheets were used to aid the discussion during the qualitative interviews, I used the layout and content of these as a template, making changes based on the responses of participants. I selected a workbook format as it was anticipated that a paper based approach would be more accessible and acceptable for carers as opposed to an electronic version, especially for those of the older age groups. I also took into account presentation guidelines as detailed below during the drafting process.

5.7.1 Presentation guidelines

The Social Care Institute for Excellence (SCIE) Accessibility Guidelines for Producing Information (Social Care Institte for Excellence, 2005) advise using simple, clear, short

sentences without any jargon including 'active and personal' language such as 'you' and 'your'. Block capitals, italics and underlining are all to be avoided where possible. They advocate the use of images to make writing easier to understand and more attractive. Images should show people from different cultures and people prefer coloured pictures as opposed to black and white. In terms of font and sizing, the guidelines suggest that 'Arial', 12 point, be used for normal text. When using the DECIDE manual, all participants will be asked if they have any visual impairment and, if they require the manual in a larger font, this will be provided.

The National Institute on Aging have produced a document 'Making your printed health materials senior friendly' (National Institute on Aging, 2007). This document advises that material produced for this demographic is precise, kept short, is easy to understand and uses everyday language and focuses on action steps. This document suggests that creators support information with real examples and relatable stories and reinforce the main points with questions. All of this guidance will be taken into consideration when creating the DECIDE manual for testing in phase two.

In the next chapter, I will discuss how I developed the DECIDE manual further through focus groups and individual interviews with community memory service professionals, to produce version two of the DECIDE manual, which was tested in a feasibility randomised controlled trial.

Chapter 6 Development of the DECIDE manual

This chapter details the next stage of the DECIDE manual development. I consulted healthcare professionals who were not involved in the development of the DECIDE manual (version one), as recommended in the IPDAS checklist (Elwyn *et al.*, 2006). In this chapter, I will detail healthcare professionals' feedback and how this informed content and layout of the DECIDE manual (version two).

6.1 Healthcare professionals' interviews and focus groups

6.1.1 Ethics committee approval

I obtained research ethics approval from National Research Ethics Service Committee London – Bloomsbury (January 2014; REC Reference: 14/LO/0012) (Appendix 4). Local NHS Research and Development approvals were obtained from; Camden and Islington NHS Foundation trust and Barnet, Enfield and Haringey Mental Health Trust (Appendix 5). All participants gave written, informed consent.

6.1.2 Recruitment

I approached healthcare professionals working in Camden, Islington and Haringey memory clinics through multidisciplinary team meetings to discuss the study with staff and explained that participants would be anonymous and they would not be identifiable in any publications. All healthcare professionals employed to work in the participating memory clinics who attend the multi-disciplinary team meetings at the time of recruitment were eligible to participate.

6.1.3 Procedure

Potential participants who expressed an interest in taking part in a focus group were given a copy of the information sheet, up to three days prior to the group meeting

(Appendix 15). If they agreed to participate they signed a consent form (Appendix 16). I invited individuals to participate in individual semi-structured interviews if they were unable to attend the focus groups.

I conducted all individual interviews, and led the focus groups, which were co-facilitated by a second researcher within participating memory clinics.

6.1.3.1 Focus group and individual interview structure

Focus groups and individual interviews followed a similar structure (see Appendix 17 for topic guide). Firstly, I gave participants a copy of the DECIDE manual (version one). I asked open questions to elicit their views on its usefulness for facilitating family carer proxy decision-making around place of care. I prompted them to comment about its content, length and design. I asked what, from their experiences, were carer's main concerns when deciding about place of care and whether these were adequately covered by the manual.

Other topics included when they felt it was most appropriate to raise and discuss living arrangements and place of care with family carers and if they thought it would be suitable for use with their current clients. To inform future implementation, I asked who within the memory clinic team would be best placed to use the manual with carers if it was found to be feasible and effective.

6.1.4 Analysis

All interviews and focus groups were digitally audio recorded and transcribed verbatim. All identifying information was removed to preserve participants' anonymity and stored on a password protected database in accordance with the Data Protection Act (1998).

I based my analysis plan on Braun and Clarke's phases of thematic analysis: familiarisation with the data, coding, searching for, reviewing and naming themes and writing-up (Braun and Clarke, 2006). I used the qualitative research software programme Nvivo 9 to code, manage and analyse all data. A second researcher and I read and re-read the transcripts to become familiar with the data then coded all data independently. We identified themes and generated a coding frame of themes from initial transcripts which we used to code subsequent transcripts. Disagreements between the researchers were resolved through discussion and a consensus was reached. I continued to recruit participants until it was judged that data saturation had been reached as no new themes were emerging from interviews.

6.2 Results

6.2.1 Demographics

Nineteen healthcare professionals participated: two in individual interviews at Haringey and Camden memory services and 17 in one of three focus groups held at each of the participating memory clinics. Participant's job titles are listed in Table 7.

Table 7: Participant's job titles

Healthcare professional job title	Number of participants
Admiral Nurse	2
Assistant Practitioner	1
Assistant Psychologist	2
Clinical Psychologist	2
Clinical Support Worker	1
Mental Health Nurse	1
Occupational Therapist	2
Old Age Psychiatrist	3
Social Worker	2
Team Manager	2
Trainee Mental Health Worker	1
Total	**19**

6.2.2 Thematic analysis

The main themes identified are detailed below.

Theme 1: Usefulness of a decision aid

Participants discussed the use of a decision aid for making proxy place of care decisions. There was agreement between participants that such a resource may help reduce anxiety and burden for families; suggested mechanisms for doing so included consolidating and documenting different family opinions:

> *"If we can do anything to reduce the family's burden and anxiety it's better for everyone around" [Focus group two]*

"They're a big family, lots of opinions, different opinions; I've been trying to pull them all together into one opinion. I think that would be really useful for that. Once that's documented, that's the opinion we go with" [Focus group one]

Several healthcare professionals suggested they would feel more confident having discussions about place of care with a decision aid as it could provide them with information, for example about financial issues, that they might otherwise not know, but be expected to know by the carer:

"'[I've had] some discussion with patients about some of these concerns, but difficultly understanding the financial assessment phase. The conversation has been difficult, not really understanding the chairlift thing, paying for it privately. If there was a leaflet that had information for me as a staff member I can more confidently talk about the financial implications" [Focus group one]

Theme 2: Content of and additions to the decision aid

Many of the participants thought that the manual should encompass decisions that enable the individual to remain at home for as long as possible and that the existing DECIDE manual (version one) focused too much on care home placement:

"I think we should be exploring about keeping people at home. We should be helping people make that decision. Actually, maybe we haven't explored carers, we haven't thought about adapting the home, maybe we need to think about that further. It might be good to have a separate leaflet or whatever, when that's sort of being explored. Then you can say 'have you thought about a care home" [Focus group one]

"Might be useful to have something about having someone at home longer keeps them well longer…That would be the nice message to send families" [Focus group three]

The participants wanted to ensure that the manual did not signpost all family carers receiving it to services for which they might not be eligible; for example, trusts are only

resourced to provide individual Occupational Therapy assessments to those in greatest need. They were concerned that families would be asking them for services they could not provide and discussed overcoming this by being ready to provide alternative services if this occurred:

> *"We shouldn't be sending the wrong message that if everyone wants it they can get it, because families will say 'well that's what we want', but they may not meet the criteria" [Focus group two]*

Theme 3: When should a decision aid be used?

Healthcare professionals thought that a decision aid should not be used at the point of diagnosis as it would be overwhelming and distressing:

> *"It might be quite scary if you've just been diagnosed and you see this and it says about going into a care home" [Focus group three]*

> *"It is dependent on the person's severities and also the carers stress, I don't think it's appropriate at the point of diagnosis" [Focus group one]*

Participants reflected that no resource is suitable for everyone and using judgement about when and when not to introduce the decision aid would be crucial:

> *"I think it's really dependent on the person. Some people it would help to get this, but other people might be so anxious about dementia and going into a home. We spend a lot of time saying 'you've got this option, that option. You're a long way from going into a home" [Focus group one]*

Clinicians said that they currently wait for people to self-identify as in need of extra support, usually through initiating further contact with the service by phone, before offering it. All who expressed a view stated they would prefer to offer the DECIDE manual in this way rather than proactively:

"I think we do it as we do it now, where people self-identify themselves that they need extra support" [Focus group one]

Theme 4: How should a decision aid be delivered?

Staff at memory clinics felt that they should deliver this intervention as they had the necessary relationship with the carer, skills and resources:

"We are quite used to doing it… It might be more difficult if it's happening in GP surgeries, as they just have that slot [only]. It's key that our contact with the patient isn't just one off, whereas GP appointments might be one off" [Healthcare professional; 01]

"[This] highlights the competency of the people doing it" [Focus group one]

Participants discussed the need to respond to cues from family carers about whether conversations with the carer alone were helpful or whether to discuss situations whilst the person with dementia was present:

"I think we're very guided by families, they tend to indicate if it's a bit of paper under the table, if we shouldn't be saying certain things... yeah and sometimes they say 'no that doesn't happen', and the family is looking at you like yes it does. So that might be a conversation to have separately" [Focus group one]

"I think we're also professional enough we can gauge a lot of the time whether somebody is telling us information which we know doesn't fit right" [Healthcare professional; 02]

Theme 5: Improvements to the DECIDE manual

Participants also gave feedback about improvements that could be made to the manual. They felt the manual would benefit from information about current available services such as Occupational Therapy, Careline and assistive technology:

"If you're going to name people you should put in OT there. They're very much key in assessing people for their needs and support etc." [Focus group one]

"For the adjustments have you considered, there are a few more things, but I don't know what's available in every trust. But here there's a lot more to consider such as Careline" [Focus group Three]

"That would be useful to put another bullet point 'assistive technology', then 'e.g., sensors" [Healthcare professional; 02]

Additionally, healthcare professionals felt that providing detail about the different types of living accommodations would be useful for carers to provide clarity about their function:

"Explain to people in a sentence what the different things mean [accommodation types]. People don't know what extra care housing or sheltered accommodation or things like that are" [Focus group one]

Finally, participants felt that the manual was not overly wordy but would benefit from the addition of pictures and clearly defined spaces for carers to respond to the prompts throughout the manual:

"I don't think it's terribly wordy, but it's all words. I personally like pictures. It helps people identify with it, when it's very wordy" [Healthcare professional; 02]

6.3 Discussion

All healthcare professionals interviewed agreed that a decision aid would be useful to facilitate conversations and decision-making about future place of care for relatives with dementia. They felt they had the skills and relationships with carers to use it. They considered that it may also be useful to consolidate and document the opinions of various family members about place of care for the person with dementia.

Healthcare professionals wanted the DECIDE manual to encompass options to keep their relative living at home for as long as possible, such as introducing more home care and assistive technology, and not focus solely on care home placement. This fits with the aims of the Prime Ministers Dementia Challenge (Department of Health, 2012). This needs to be balanced with the need, which led to this project, to reduce conflict and distress in family carers deciding about care homes, whatever decision they make. Many people have already exhausted other options.

6.4 DECIDE Manual: version two

6.4.1 Alterations to version one of the DECIDE manual

Using the findings above, I amended the DECIDE manual (version one) to produce version two for testing in my feasibility randomised controlled trial (see Appendix 14 and 18).

6.4.1.1 Changes to structure and layout

I reduced the amount of text in the manual and simplified the language wherever possible. I added text boxes to the DECIDE manual to record carers' responses to the various questions throughout. I added relevant pictures throughout the manual.

6.4.1.2 Changes to content

I added information to the manual citing adjustments that could be made at home to increase focus on maintaining people living there for as long as possible, including Occupational Therapy and assistive technology. I also added information about the dementia advisor and navigator services.

I expanded the section on different types of living accommodation, explaining in detail what the different types are rather than simply listing them. In addition, I added more

detail on the financial assistance available for carers, especially in relation to benefit support.

Another challenge of creating the DECIDE manual was that different geographical areas offer different services for carers and, in some instances, this is based upon the carers financial situation so will vary for each individual. Although I aimed to tailor the manual to be relevant for local services (in terms of logos or contact information), it was important that the DECIDE manual provided generic information to carers and, that as they were guided through, they were reminded that these options were relative to which services were available in their area and relevant to their circumstances. I gave nationwide dementia service contact information, including a description of what these services do, in order to try and make the manual as applicable to as many people as possible.

6.4.2 DECIDE Pilot

I then asked three family carers of people with dementia to pilot version two of the DECIDE manual. Two were daughters of people with dementia and the third was a wife whose husband has dementia. One of the daughters and the wife who took part in piloting were caring for their relative at home and currently making decisions about where their relative should live in the future. The second of the daughters had a mother who had just moved to a care home. I met the carers individually and we completed the DECIDE manual. I asked carers to fill in the manual in relation to their current situation with their relative with dementia and I asked them to comment about the content, structure and appearance of the manual as we went through it.

In all three cases, the discussion took less than an hour. This suggested that completion of the manual without discussion of content for piloting would take approximately 30-45 minutes. One family carer suggested that I add a summary page where the discussion could be written down by the researcher once the manual was completed

and I did this. Additionally, carers felt that the word 'toolkit' used on version one of the DECIDE manual was confusing and should be changed to 'manual'.

6.4.3 Structure the DECIDE manual (version two)

Following the changes mentioned above, the DECIDE manual (version two) (Appendix 18) was created. It is 13 pages long and begins with a cover sheet explaining the purpose of the manual. It comprises three sections:

- Section one, 'Where to live in the future', elicits concerns about the current living environment and carer's own health and other concerns. It discusses strategies to maximise potential for the person continuing to live at home and support for carers; the person with dementia's previous wishes are discussed; information regarding different types of accommodation and financial support information is covered.
- Section two provides a useful contacts list.
- Section three summarises main points of the discussion.

The manual was printed in colour and is available in larger fonts, if requested. Once the manual is completed with carers they will keep it.

Chapter 7 Methods for feasibility randomised controlled trial

In this chapter I will describe the method for the feasibility Randomised Controlled Trial (RCT) conducted with family carers of people with dementia to evaluate the DECIDE manual (version two). Trial registration: ISRCTN58368696.

7.1 Ethics committee approval

I obtained research ethics approval for the study from National Research Ethics Service Committee North East – Newcastle & North Tyneside 2 (January 2015; REC Reference: 15/NE/0015) (Appendix 19). Local approval was obtained from all areas where the study was conducted; East London NHS Foundation Trust, Camden and Islington NHS Foundation Trust and Barnet, Enfield and Haringey Mental Health NHS Trust (Appendix 20). All participants gave written, informed consent.

7.2 Recruitment

I recruited family or friend carers of people with dementia to the study between May 2015 and January 2016 from four memory clinics across three London boroughs. They were Camden Memory Service and Islington Memory Assessment and Treatment Service within Camden and Islington NHS Foundation Trust; Haringey Memory Service within Barnet, Enfield and Haringey Mental Health Trust and Tower Hamlets Diagnostic Memory Clinic within East London NHS Foundation Trust.

Clinicians working within the memory clinics identified carers of people with memory problems and gave them an information sheet (Appendix 21). In line with the Mental Capacity Act (2005), we assumed that the carers had capacity unless there was evidence to the contrary. If the clinicians or researchers at any point judged an individual lacked capacity, as defined by the Mental Capacity Act, they were excluded from participation in the study.

I telephoned potential participants who were interested in the study and had agreed to be contacted to discuss the study further and arrange an interview if they wanted to participate. Interviews were conducted in a location convenient to the participant, either in their own home or in appropriate university buildings. All participants gave written, informed consent (Appendix 22).

7.3 Sample

Participants were current, unpaid, main family or friend carers of people who were patients of memory clinics in inner and outer London and had a clinical diagnosis of dementia. I sought to recruit a demographically diverse range of carers (in terms of sex, relationship to the person with dementia and ethnicity).

7.3.1 Participant inclusion/exclusion criteria

Inclusion criteria for family carers were:

- Current, unpaid, main informal carer (e.g. family member or friend in regular contact who is either next of kin or a 'key decision maker') for people with moderate or severe dementia (MMSE <20) not currently living in residential care OR carers of people with any severity of dementia where the clinician is aware that the carer is currently considering decisions around place of care.
- English language skills sufficient to participate in interviews. Whilst it is acknowledged that the ideal would be to use the first language of all potential participants, unfortunately I did not have funds for interpreters.

Exclusion criteria for family carers were:

- Carers under the age of eighteen.
- Carers where there are clinical concerns that may preclude them from being approached such as severe physical or mental illness.

- Carers judged unlikely to have capacity to give informed consent.

7.3.2 Sample size

My sample size calculation was based on the primary aims of the study, to evaluate feasibility of a future pragmatic, randomised trial in terms of recruitment, acceptance of randomisation and attrition. I aimed to recruit 40 carers, 20 into each arm. I based my sample size on two previous trials evaluating the use of a decision aid for 1) family carers of people with dementia making choices about community services, particularly respite care (Stirling *et al.*, 2012) and 2) long-term tube feeding in cognitively impaired older persons (Mitchell *et al.*, 2001). These studies recruited 31 carers across the two arms of the trial and 15 carers for the intervention only trial respectively. Sample size recommendations from the Ottawa guidelines of developing and evaluating patient decision aids were also considered, suggesting about 30 individuals per group in a before and after study (O'Connor and Jacobsen, 2003).

This is a feasibility study and therefore I did not expect to have the necessary power to show significant differences between the two groups. If looking for an effect size of 0.4 for the total Decisional Conflict Scale score, as has been previously judged a clinically important difference (O'Connor, 1993), I would need a sample size of 200 participants (100 in each arm).

7.3.3 Joint carers

In some instances, multiple family members share caring responsibilities for the person with dementia equally. Where this occurred, families were given the option to be interviewed separately as individual participants or for one person to take part. Additional family carers were welcomed to be in attendance during assessments but the research outcome was measured only with the pre-agreed main participant.

7.4 Procedure

All participants completed assessments at baseline, a follow-up telephone interview at least one week later and a face-to-face follow-up interview 10 weeks after the baseline date. Figure 5 illustrates the trial structure. This visit schedule was agreed upon in order to measure any immediate effect of the DECIDE manual and also more long-term effects.

7.4.1 Randomisation

Following informed consent, all participants were individually randomised into one of two groups; either intervention or treatment as usual. Computerised randomisation was overseen by a departmental administrator independent of the trial using the online software 'Sealed Envelope' (http://www.sealedenvelope.com).

7.4.2 Blinding

I was the only individual carrying out the research and collected both the standardised measures and completed the DECIDE manual with carers. I was therefore not blind to randomisation status. Due to the nature of the intervention being delivered, I was also unable to blind participants to treatment group.

7.4.3 The DECIDE intervention

The content and delivery method for the DECIDE manual is detailed in Section 6.4.3. The manual was amended to include the correct NHS trust logos and information about local services for each of the four recruiting memory services. I read through the contect of the manual and discussed each page with participants, promopting consideration and completion of the necessary questions and sections to be 'filled-in' throughout. If during the discussion participants had specific questions about changes or services they would like further information about I would sign-post to the necessary

service or clinican at the memory services. This 'completed' version of the manual was then given to the participants to keep for future reference.

7.4.4 Treatment as usual

The control condition was treatment as usual as is recommended for trials in the MRC developing and evaluating complex interventions guidance (2008). In this instance none of the memory clinics currently use specific, structured resources for discussing place of care decisions with carers of people with dementia. With this in mind, for those in this group, the Alzheimer's Society factsheet 'Selecting a care home' was given to participants following consent and completion of baseline measures. Participants were left with this information to read in their own time and they were advised to speak with their clinicians if they wanted to discuss decision-making around long-term care for their relative further.

7.5 Outcome measures

I recorded the number of potential participants referred to me by healthcare professionals who did and did not agree to participate in the trial and participant retention in the trial.

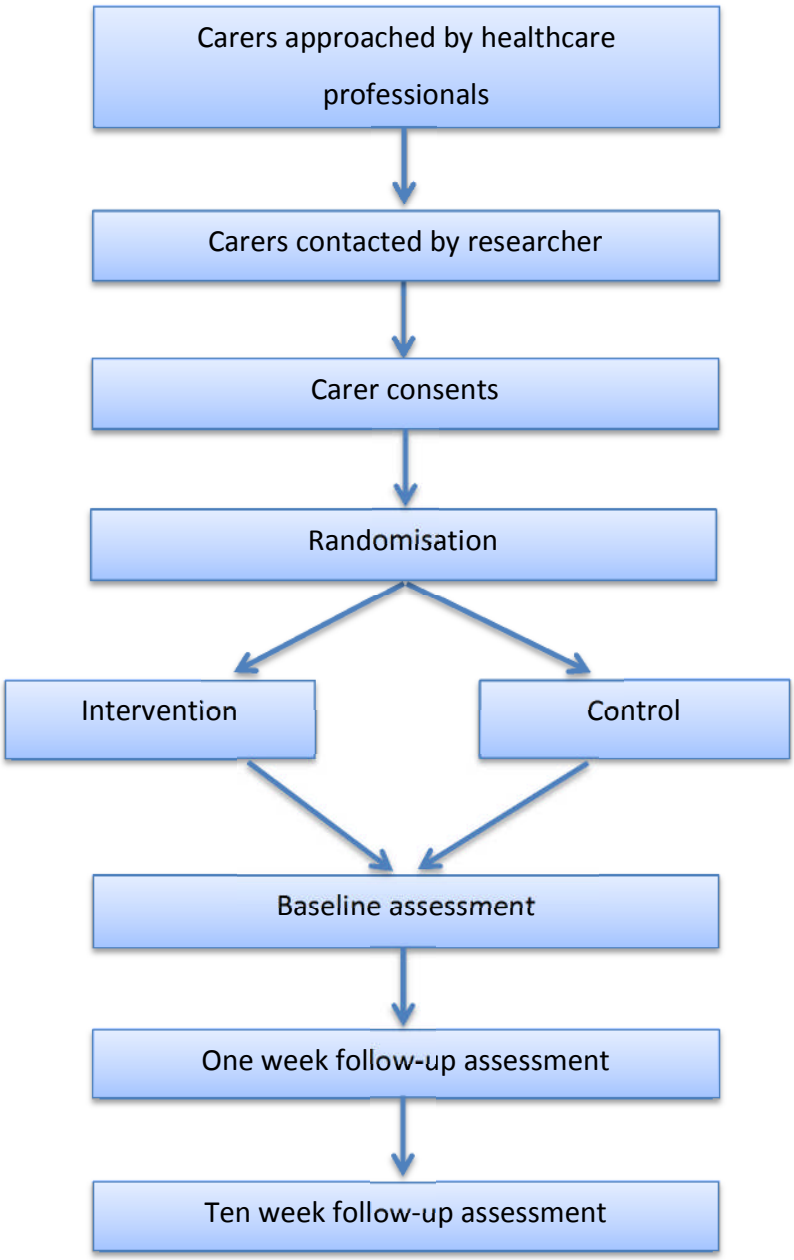
7.5.1 Socio-demographic data

At baseline assessment, for all participants, I recorded: age; sex; ethnicity; marital status; relationship to the person with dementia; current or previous occupation; number of year's education; current living situation of the carer and their relative with dementia; and, use of any dementia specific services such as paid carers, attending a day centre or befrienders.

7.5.2 Standardised measures

At baseline, one week and 10 week follow up assessments, carers completed the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983) and the Decisional Conflict Scale (DCS) (O'Connor, 1995).

Figure 5: DECIDE feasibility randomised controlled trial structure



7.5.2.1 The Hospital Anxiety and Depression Scale (HADS)

The HADS (Zigmond and Snaith, 1983) assesses how respondents have been feeling in the preceding week; it consists of two seven-item sub-scales, with each item scored 0-3, resulting in scores for anxiety (0-21) and depression (0-21) (Appendix 23). It has been shown to be valid and reliable in assessing symptom severity and caseness of anxiety and depression in somatic, psychiatric and primary care patients and in the general population. An optimal balance between sensitivity and specificity was achieved when caseness was defined as a cut-off score of 8 or above on both the anxiety and depression sub scales (Bjelland *et al.*, 2002).

7.5.2.2 Decisional Conflict Scale

Decisional conflict describes uncertainty about a course of action. The Decisional Conflict Scale (O'Connor, 1995) measures: personal perceptions of uncertainty in choosing options; factors contributing to uncertainty such as feeling uninformed; lack of clarity about personal values; feeling unsupported in decision-making and perceived effective decision-making. Participants are required to state which treatment or care option they prefer and consider this preferred option when completing the scale. In this trial the options are: no care package at home, paid carers, extra care sheltered housing, care home or unsure. The scale comprises 16 items, each scored 0-4 (Appendix 24). Total scores are expressed as a percentage of the maximum possible score, ranging from 0 (no decisional conflict) to 100 (extremely high decisional conflict). Scores of 25 or lower have been associated with making and implementing decisions and scores that exceed 37.5 associated with delay in decision-making or implementation (O'Connor *et al.*, 1998).

Five sub-scale scores are also calculated, and these are also expressed as a percentage of the total possible sub-scale score. The 'Uncertainty' sub-scale score is calculated using questions 10, 11 and 12 of the Decisional Conflict Scale. Scores for this scale range from 0 (feels extremely certain about best choice) to 100 (feels extremely

uncertain about best choice). The 'Informed' sub-scale score is calculated by summing questions 1, 2 and 3 of the scale with a score of 0 reflecting feeling extremely informed to 100 feeling extremely uninformed. The 'Values' sub-scale score is calculated using items 4, 5 and 6 ranging from a score of 0 (feeling extremely clear about personal values of the benefits and risks/side effects) to 100 (feels extremely unclear about personal values). The 'Support' sub-scale score is calculated using questions 7, 8 and 9. A score of 0 reflects feeling extremely supported in decision-making and a score of 100 reflects feeling extremely unsupported in decision-making. Finally, questions 13, 14 and 15 create the 'Effective decision' sub-scale score. A score of 0 is classified as a good decision, a score of 100 as a bad decision.

The Decisional Conflict Scale has good psychometric properties in terms of reliability (Cronbach's alpha coefficients > 0.78) and construct validity (discriminates between those who make and delay decisions; effect size ranges of 0.4 to 0.8). The scale is sensitive to change; of the sub-scales, the 'Informed' sub-scale most consistently discriminates between different decision supporting interventions (effect size 0.3 to 0.4) (O'Connor, 1993).

7.5.3 Intervention only measures

7.5.3.1 Quantitative measures

Participants in the intervention group completed a short evaluation of the DECIDE manual immediately after completion. The quality of the information in the manual was rated using a five point Likert scale with a score of one for poor quality and a score of five for excellent quality. Relevance of the information was rated using a five point Likert scale ranging from a score of one for little relevance to five for great relevance. Usefulness of the decision aid for carers to discuss living arrangements and future place of care for people with dementia was also rated on a 10 point Likert scale with a score of one for very unuseful to a score of 10 for very useful (Appendix 25).

7.5.3.2 Qualitative interview

At the 10 week follow-up assessment, all intervention group participants were invited to take part in a semi-structured qualitative interview (see Appendix 26 for interview topic guide) to explore their experiences of the intervention and whether and how they had found it useful in making decisions about place of care and any improvements they would suggest (with prompts around content, appearance and length). I also asked when and from whom they would like to have received this intervention in the past.

7.6 *A priori* analysis plan

7.6.1 Quantitative

All statistical analyses were performed using SPSS 22 software package (Incorporated, 2013). I wrote an *a priori* analysis plan which I outline below. I agreed this with both of my supervisors before commencing analyses.

All quantitative tests were two-sided and conducted at the 5% level of significance. I carried out an intention-to-treat analysis using last observation carried forward in place of missing data.

7.6.2 Recruitment and retention

I report the proportion of carers approached by healthcare professionals who subsequently agreed to participate in the study, their sex and relationship to the person with dementia. Additionally I report the proportion of people who carried out baseline interviews who also completed the measures at the 10 week follow-up assessment. Predetermined criteria for assessing the success of this feasibility trial are (Carroll *et al.*, 2013):

1) Participant recruitment rate of at least 80% of all eligible carers.

2) Successful delivery and completion of the DECIDE manual in 80% of consented participants.

3) Questionnaire completion rate at all three time points of at least 80% of all participants.

7.6.3 Descriptive analyses

I report the socio-demographic characteristics of all participants.

7.6.4 Primary outcomes

In order to test my primary hypothesis, I report the proportion of family carers who receive the DECIDE manual who report finding it relevant (defined *a priori* as a score of 4 or 5 on a 5 point Likert scale). I also report the proportion of family carers who receive the DECIDE manual who report finding it useful (defined *a priori* as a score of 8, 9 or 10 on a 10 point Likert scale), for both of which I reported the standard deviations (Teri *et al.*).

7.6.5 Secondary outcomes

Results from all secondary analyses were treated as exploratory. I tested my secondary hypothesis that family carers who receive the DECIDE manual intervention will report lower scores on the total Decisional Conflict Scale score and Informed sub-scale score, when compared to family carers in the treatment as usual group 10 weeks post baseline. I tested whether Decisional Conflict Scale score approximated the normal distribution graphically and statistically, through evaluating skewness and kurtosis, to determine where to use parametric or non-parametric tests of significance. In line with standard practice, I defined a skew statistic >1 or <-1 as within acceptable limits for approximating the normal distribution. I also compared HADS scores, all other

decisional conflict sub-scale scores and the preferred place of care as stated in the Decisional Conflict Scale between groups.

7.6.6 Qualitative

All interviews were digitally audio recorded and transcribed verbatim. All identifying information was removed to preserve participants' anonymity and stored on a password protected database in accordance with the Data Protection Act (1998).

As with the previous qualitative analysis in this PhD, I based my analysis plan on the phases of analysis outlined by Braun and Clarke (Braun and Clarke, 2006). The qualitative research software programme Nvivo 9 was used to code, manage and analyse all data. A second researcher and I thematically coded all data independently to ensure reliability, generating a coding frame from initial interviews using a thematic content analytic approach. Disagreements between the researchers were resolved through discussion with each other and a consensus was reached. Participants were offered the opportunity to make any alterations to their own transcripts so that I knew it was a true record of what they intended to say and they were able to elaborate if they wished as a method of quality control and validation. No participants took the opportunity to review their transcripts.

I will now present the results of the mixed-methods feasibility randomised controlled trial in Chapters eight (quantitative findings) and nine (qualitative findings).

Chapter 8 Feasibility randomised controlled trial: quantitative results

8.1 Trial recruitment

41 (85%) of the 48 carers referred to the study completed baseline measures and were randomised. Of the seven who did not participate, four were uncontactable and three declined because they or the person with dementia were unwell. Four of the seven non-participants were women and five were children of the person with dementia (Table 8). 21 participating carers were randomised to the control arm and 20 to the intervention arm. One carer was uncontactable after completing the baseline assessment and being randomised to the control group; the other 40 (98%) participants completed the study.

Table 8: Characteristics of people referred to the study that completed baseline measures compared to non-participants

		Non-participants *n* (%)	All participants *n* (%)
Recruitment site	Barnet, Enfield and Haringey	1 (14)	15 (37)
	Camden	2 (29)	12 (29)
	East London	2 (29)	7 (17)
	Islington	2 (29)	7 (17)
Sex	Male	3 (43)	15 (37)
	Female	4 (57)	26 (63)
Relationship to person with dementia	Spouse or partner	2 (29)	17 (42)
	Child	5 (71)	24 (58)
Total		**7**	**41**

8.2 Demographics

Demographics of all participants who were randomised are shown in Table 9. Just over half (*n* = 24; 58%) of participants were adult children of people with dementia. Approximately half of the carers lived with their relative with dementia at the time of participation. 71% of participants were of White British ethnicity.

8.3 Primary outcomes

8.3.1 Relevance and usefulness of the DECIDE manual

All 20 carers allocated to the intervention group rated the DECIDE manual as 4 (*n*=8) or 5 (*n*=12) on the 5 point Likert scale of relevance (mean = 4.60, SD = .503) indicating that they found it very relevant to them and their relative.

On the 10 point Likert scale of usefulness of the DECIDE manual, 1 carer rated the manual as 7, 6 carers rated it as 8, 1 rated it as 9 and 12 rated it as 10 (mean = 9.20, SD = 1.06), indicating that they considered the manual useful or very useful.

Table 9: Participant characteristics

		Intervention arm (*n*=20) *n* (%)	Control arm (*n*=21) *n* (%)
Sex	Male	5 (25)	10 (48)
	Female	15 (75)	11 (52)
Age (years)	40-54	5 (25)	7 (33.3)
	55-64	7 (35)	7 (33.3)
	65-74	5 (25)	4 (19)
	75-84	3 (15)	3 (14.3)
Relationship to person with dementia	Spouse or partner	10 (50)	7 (33)
	Child	10 (50)	14 (67)
Carer and person with dementia currently live together?	Yes	11 (55)	10 (48)
	No	9 (45)	11 (52)
Ethnicity	White British	16 (80)	13 (62)
	Other White	3 (15)	3 (14)
	Asian	1 (5)	2 (9)
	African-English	0 (0)	1 (5)
	Black Caribbean	0 (0)	1 (5)
	Other: Hispanic mixed	0 (0)	1 (5)

8.4 Secondary outcomes

8.4.1 Decisional Conflict Scale (Table 10 and Figure 6)

The Decisional Conflict Scale total score data approached a normal distribution; skewness of -.47 (Standard Error = .37) and kurtosis of .087 (Standard Error = .72). This

was the case for the all Decisional Conflict Scale sub-scales (see Appendix 27 for sub-scale data). I therefore used parametric tests of significance.

Using independent *t*-tests of significance, there was no significant difference in mean total Decisional Conflict Scale score between the intervention and control groups at baseline (mean difference = -0.89, 95% CI [-9.61, 7.83], t(39) = 0.21, p = .838).

At 10 week follow-up, the intervention group (mean = 24.72) had a significantly lower mean total Decisional Conflict Scale score when compared with control group participants (24.72 compared to 36.68; mean difference = -11.96, 95% CI [-20.10, -3.83], t(39) = -2.97, p = .005). The difference between groups in Decisional Conflict Scale total scores at 10 week follow-up remained significant after controlling for baseline scores (ANCOVA F(1,38) = 12.38, p = .001).

8.4.2 Decisional Conflict Scale sub-scale scores

Table 10 provides the mean scores of all Decisional Conflict Scale sub-scales. There was no significant difference between the intervention and control groups at baseline on any of the five sub-scale scores; uncertainty (mean difference = -3.35, 95% CI [-18.76, 12.07], p = .663), informed (mean difference = .711, 95% CI [-10.536, 11.80], p = .897), values (mean difference = 2.86, 95% CI [-6.59, 12.31], p = .544), support (mean difference = 3.87, 95% CI [-9.43, 17.16], p = .560) and effective decision (mean difference = -6.45, 95% CI [-16.84, 3.94], p = .217).

At 10 week follow-up, participants who received the DECIDE manual felt, compared with carers in the control group, significantly more informed (mean difference = -12.95, 95% CI [-22.14, -3.76], p = .007); more clear about their own values (mean difference = -10.20, 95% CI [-19.51, -.848], p = .033); more certain about their decision (mean difference = 16.60, 95% CI [-29.30, -3.91], p = .012) and that that they had made a significantly more 'effective' decision (mean difference = -14.54, 95% CI [-23.83, -5.24],

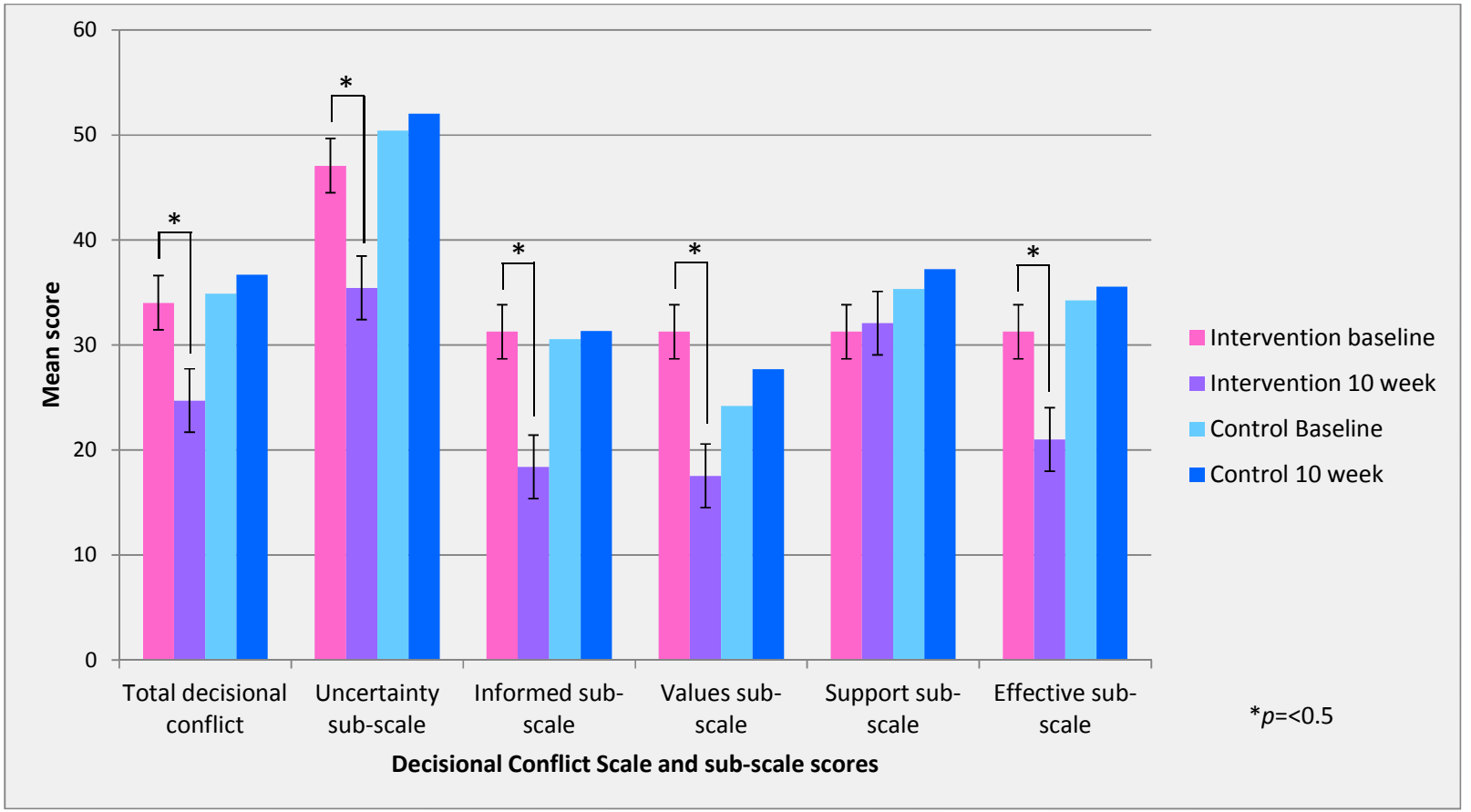
p = .003). There was no significant difference between groups on the sub-scale of feeling supported (mean difference = -5.12, 95% CI [-18.69, 8.44], *p* = .450).

Table 10: Decisional Conflict Scale and sub-scale mean scores

Participant arm								
Decisional Conflict total and sub-scale (0-100)	**Intervention (*n*=20) Mean (Teri *et al.*)**			**Control (*n*=21) Mean (Teri *et al.*)**			**Intervention vs Control at baseline**	**Intervention vs Control at 10 weeks**
	Baseline	**1 week**	**10 week**	**Baseline**	**1 week**	**10 week**		
Total Decisional Conflict Score	34.02 (16.04)	32.82 (16.10)	24.72 (13.55)	34.90 (11.29)	33.31 (11.88)	36.68 (12.20)	t(39) =-0.206, *p* = 0.838	t(39) =-2.974, *p* = 0.005*
Uncertainty sub-scale	47.07 (27.00)	45.80 (25.50)	35.43 (20.11)	50.41 (21.66)	49.57 (20.84)	52.03 (20.14)	t(39) =-0.439, *p* = 0.663	t(39) =-2.646, *p* = 0.012*
Informed sub-scale	31.27 (19.10)	28.75 (17.20)	18.37 (16.14)	30.56 (15.90)	28.97 (16.60)	31.32 (12.88)	t(39) =0.130, *p* = 0.897	t(39) =-2.851, *p* = 0.007*
Values sub-scale	27.05 (16.42)	27.10 (16.65)	17.53 (15.74)	24.19 (13.40)	23.40 (12.52)	27.71 (13.80)	t(39) =0.612, *p* = 0.544	t(39) =-2.206, *p* = 0.033*
Support sub-scale	39.18 (25.85)	37.07 (25.03)	32.10 (23.73)	35.32 (15.13)	32.54 (15.35)	37.22 (19.10)	t(39) =0.588, *p* = 0.560	t(39) =-0.764, *p* = 0.450
Effective sub-scale	27.80 (19.50)	25.92 (18.40)	21.00 (13.73)	34.25 (12.92)	32.46 (13.66)	35.54 (15.60)	t(39) =-1.255, *p* = 0.217	t(39) =-3.164, *p* = 0.003*

* = statistically significant result

Figure 6: Decisional Conflict Scale and sub-scale mean scores at baseline and 10 week follow-up



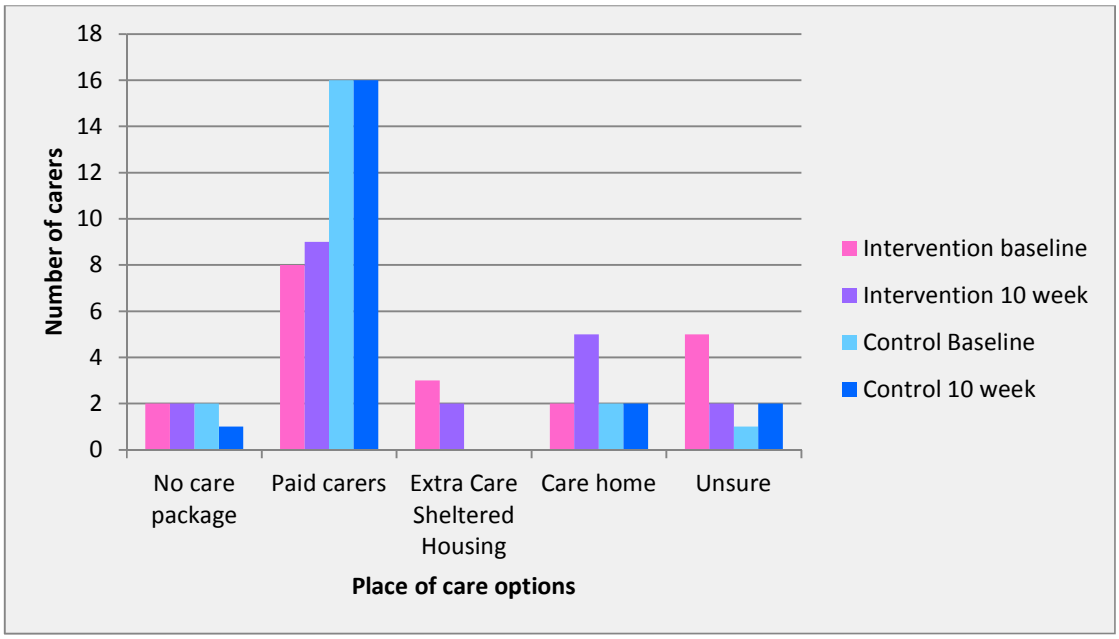
8.4.2.1 Decisional Conflict Scale: preferred place of care (Figure 7)

At baseline 40% (*n*=8) of carers in the intervention arm and 76% (*n*=16) of carers in the control arm wanted their relative to remain at home with access to paid carers.

Four carers in the intervention arm changed their preferred place of care between baseline and the 10 week follow-up. Two carers who were 'unsure' at baseline preferred a care home for their relative at 10 weeks. One carer who was 'unsure' now preferred paid carers. One carer who had originally preferred extra care sheltered housing now preferred a care home placement for their relative.

In the control arm one carer changed their preference at the 10 week follow-up from their relative remaining at home to 'unsure'.

Figure 7: Carers preferred place of care for their relative with dementia



8.4.3 Hospital Anxiety and Depression Scale (HADS) (Table 11)

At baseline, there was no significant difference in anxiety (mean difference = .269, 95% CI [-2.51, 3.05, *p* = .846) or depression scores (mean difference = 1.33, 95% CI [-1.33, 3.98], *p* = .319) between the two groups.

Similarly at 10 week follow-up, there was no significant difference in anxiety (mean difference = -.024, 95% CI [-2.94, 2.89], *p* = .987) or depression scores (mean difference = .421, 95% CI [-2.23, 3.10], *p* = .750) between the two groups.

Table 11: Hospital Anxiety and Depression scale mean scores

Hospital Anxiety and Depression Scale (0-21)	Intervention (*n*=20) Mean (Teri *et al.*)			Control (*n*=21) Mean (Teri *et al.*)		
	Baseline	**1 week**	**10 week**	**Baseline**	**1 week**	**10 week**
HADS-Anxiety Sub-scale	8.65 (4.20)	8.40 (3.90)	8.50 (4.24)	8.38 (4.60)	7.67 (4.59)	8.52 (4.94)
HADS-Depression Sub-scale	5.85 (3.73)	5.50 (3.72)	5.85 (3.63)	4.52 (4.61)	4.52 (4.52)	5.43 (4.67)

I will now describe the qualitative findings from the feasibility randomised controlled trial and the DECIDE manual final development stage (Chapter nine).

Chapter 9 Qualitative interviews and further development

I qualitatively interviewed participants in the intervention arm of the trial at the 10 week follow-up visit about their experiences of the intervention, whether and how they had found it useful and any improvements they would suggest. In this chapter, I describe the results of these interviews and the subsequent final development stage of the DECIDE manual (version three).

9.1 Qualitative interviews

I have described the main themes identified below and summarised these in Figure 8. Participant characteristics are detailed in Table 9 (Chapter 8).

9.1.1 Thematic analysis

Theme 1: Has the DECIDE manual helped with decision-making?

Information about options:

Participants were asked if completing the DECIDE manual had helped them during the decision-making process. Most of the carers (*n*=14) felt that it had helped them by informing them about the options available and providing an opportunity to discuss them:

> *"Yea it's definitely given us what the options are because you never know for certain so it has sort of opened your eyes to what the options are" [Daughter of person with dementia; 024]*

> *"The reality is there is a slowly downward spiral and at each level of the spiral something else becomes impossible to do and you have to make decisions, re-evaluate the current decision to see if it's still valid and the [DECIDE] manual enabled me to do that" [Son of person with dementia; 023]*

A structure to think things through:

Carers also felt the process of completing the DECIDE manual by recording their thoughts and taking time to reflect on these was useful:

> *"So I did find it very helpful [the DECIDE manual], the exercise of doing it" [Daughter of person with dementia; 021]*

For some carers the manual helped them focus on the decision of where their relative lives and this was helpful:

> *"I think it may have provided a trigger you know for me to think more seriously about it" [Wife of person with dementia; 02]*

Regret about not having decided before:

Many participants regretted not having future place of care discussions with their relatives earlier on in their illness and would have appreciated help in initiating these conversations, they felt that the DECIDE manual would be a way of doing so:

> *"I think what would have really helped…it would have been this conversation happening 10 years ago with mum so that mum had different options and knew what would have happened" [Daughter of person with dementia; 032]*

> *"I just think it's so much easier if one can kind of work out a way to gently make the thing less frightening and how to approach it… also how we're going to tell mum because I don't want to tell her forthrightly because I don't think she'll go. And I don't want to over upset her" [Daughter of person with dementia; 035]*

DECIDE was not always helpful:

Some carers felt that it had not helped them make decisions (*n*=6) but still found that the information was useful:

> *"There was some helpful information in the booklet but it probably didn't help us with the decision" [Son of person with dementia; 04]*

> *"Well no it hasn't but I'm not sure that anything would have done to be honest" [Male partner of person with dementia; 05]*

Some of the carers who found the information helpful but that it did not lead to a decision appeared from their responses, to have made a decision against a move to a care home at the current time, but may not have identified this as a decision:

> *"So yea I'm coming to understand that I think a care home eventually will be the answer, I'm not sure I want it to happen too soon… So I'm letting sleeping dogs lie a bit at the minute" [Wife of person with dementia; 01]*

> *"I think a care home is still on the cards but not right now because right now he's not gone enough, when he's gone enough, when he doesn't know any better then that's the road I'm going to have to go down" [Wife of person with dementia; 08]*

Theme 2: How did DECIDE facilitate decision-making?

Discussion with a third party

Carers talked about the importance of contact with a professional advisor, external to the family, during the decision-making process and welcomed the opportunity for reflection with a third party that the DECIDE manual provided:

> *"I think it's just seeing somebody regularly and you know seeing [Admiral Nurse] regularly has helped me" [Wife of person with dementia; 02]*

"Well I think contact is important [from healthcare professionals]" [Male partner of person with dementia; 05]

"If you're someone emotional it is good to have someone to support your decision outside of your family to say 'you're making the right decision' and give that support. It's difficult without that" [Son of person with dementia; 04]

Acknowledging impact of the decision on carers own lives

Carers, in particular spouses, spoke of the impact of the decision on their own lives and their relationship with the care recipient:

"I'm just finding it harder to treat it as something separate from me you know…It's a bigger impact on my life and how I see his life. I don't want to see his life as separate from me as I would, I don't mean it horribly, like my mum or my dad or my brother or my sister. I want to be more a part of his life, the new life that he's going to have" [Wife of person with dementia; 01]

"It's like your whole world disintegrates. And the life you know is gone, everything's been turned upside down on its head and I think for the partner it's hard. It's hard because you just think what am I supposed to do, where do I go, who do I talk to?" [Wife of person with dementia; 08]

Theme 3: Ongoing barriers to decision-making

Despite the perceived benefits of the DECIDE manual, some barriers to decision-making remained as outlined below.

Difficulty involving the person with dementia

Carers spoke about the challenges they faced in discussing future place of care with their relative with dementia. In some instances this resulted in carers excluding the person with dementia from the decision-making process:

"I couldn't tell her about the move to this place [sheltered housing]" [Son of person with dementia; 04]

"One of the problems I have with mum is that if I raise something, it's going to start praying on her mind so I've got to be very careful how I raise it" [Daughter of person with dementia; 021]

Difficulty with family shared decision

Carers spoke of the importance of making the decision as a family, but also the difficulties of doing so:

"I think it should be a family decision and I think everybody should be involved and all the options clearly laid out right at the beginning" [Daughter of person with dementia; 035]

"Family are very emotional and what you are deciding and doing is tough" [Son of person with dementia; 04]

Carers discussed the pressure from other family members to make the decision about putting the person with dementia into a care home:

"I feel as though I'm under a greater pressure now in a way because, the pressure comes from outside [the wider family]" [Male partner of person with dementia; 05]

"It's hard, it's like every day you've got pressures on you from others that you've got to cope with and I just get frustrated with it because there's no escape" [Wife of person with dementia; 08]

When there was multiple family members involved, carers recognised that the primary carer needed support from other members however this did not always happen:

"I think it's much harder for the person that's doing the day to day caring I feel and mum does go up and down and you try and support her more, her needs change well" [Daughter of person with dementia; 024]

"The thing is that everyone is frantic with their lives so they don't want to deal with it… I call it wilful blindness, they don't want to see how bad it is" [Daughter of person with dementia; 035]

Unclear service structures and networks

Some participants expressed continued confusion, despite receiving the DECIDE intervention, about healthcare professional's roles and whom they should contact when they needed advice and support:

"But I don't know what people's roles are, which is also confusing" [Male partner of person with dementia; 05]

"That is my single biggest problem, is who you speak to about caring" [Daughter of person with dementia; 021]

"Maybe it's about the services being more proactive" [Daughter of person with dementia; 021]

"It's very difficult for them so as long as you know that they're there then it's up to you to raise it. They can't be proactive with everyone because they'd just be swamped wouldn't they" [Daughter of person with dementia; 024]

The system or a crisis forced the decision

Carers felt that the care home placement system (knowledge of waiting lists and concerns over availability of a place) forced their decision-making about when their relatives go to live in a care home:

"I didn't know that anyone else would offer me a place when I wanted it, which is always the case and I was really very keen not to hang on until something awful happened to one or other of us" [Wife of person with dementia; 02]

"After we called they said we had to move in five days" [Son of person with dementia; 04]

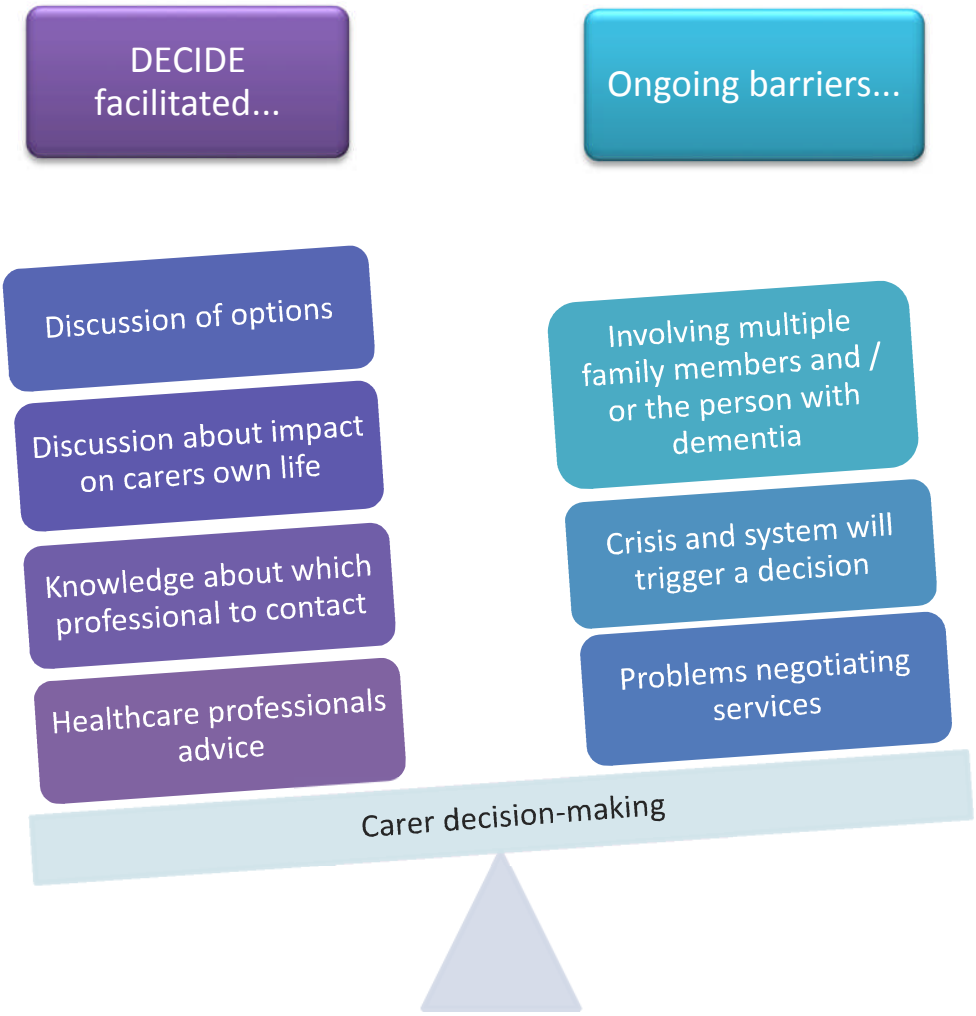
"It's the time scale issue that, I know that it takes time to find places that are good and you often have waiting lists" [Daughter of person with dementia; 035]

Rather than actively making a decision, several carers said that they would rather wait to make the decision when there was no other choice and felt that a crisis would ultimately force them to make a decision:

"So yea I'm coming to understand that I think a care home eventually will be the answer, I'm not sure I want it to happen too soon… So I'm letting sleeping dogs lie a bit at the minute" [Wife of person with dementia; 01]

"I think a care home is still on the cards but not right now because right now he's not gone enough, when he's gone enough, when he doesn't know any better then that's the road I'm going to have to go down" [Wife of person with dementia; 08]

Figure 8: Decision-making factors facilitated by the DECIDE manual and ongoing barriers



Theme 4: How can DECIDE be further improved to help facilitate decision-making?

I asked for feedback on the content, layout and structure of the DECIDE manual for the final phase of development. One carer suggested that rather than using the word 'relative' throughout the manual when referring to the person with dementia, that it would be better to leave a blank space to insert the individual with dementia's name as this would feel more personal and relevant. It was also suggested that the summary

section at the end of the manual would be better placed at the beginning for ease of reference. A number of carers stated that in hindsight they would like to have been given their copy of the DECIDE manual before the baseline visit so they had some time to read through it alone prior to our completion together. These final changes have been incorporated and version three of the DECIDE manual created (see Appendix 28).

Chapter 10 Discussion

In this chapter, I discuss the quantitative and qualitative findings from the feasibility randomised controlled trial detailed in Chapters eight and nine. I also provide details of alternative study designs and critique the DECIDE manual against the International Patient Decision Aid Standards checklist (Elwyn *et al.*, 2006).

10.1 Main findings

10.1.1 Primary outcomes: recruitment, retention, relevance and usefulness

Carers of people with dementia who were currently making decisions about where their relative should live in the future, or whose relatives had moderate to severe dementia, were willing to take part in the study. Healthcare professionals working at memory clinics were willing to assist with recruitment and I recruited to time and target. Most eligible carers referred to the trial agreed to be randomised. The feasibility randomised controlled trial met all *a priori* criteria for success in the following ways:

> *Criteria 1) Participant recruitment rate of at least 80% of all eligible carers:* I recruited 85% (41/47) of all eligible carers referred by the clinical teams.
>
> *Criteria 2) Successful delivery and completion of the DECIDE manual in 80% of consented participants:* 100% (*n*=20) of participants randomised to the intervention successfully completed the DECIDE manual.
>
> *Criteria 3) Questionnaire completion rate at all three time points of at least 80% of all participants:* 98% of consented participants (*n*=40) completed all three study assessments.

Following completion of the DECIDE manual, all carers reported finding it very relevant (defined *a priori* as a score of 4 or 5 on a 5 point Likert scale) and useful (defined *a*

priori as a score of 8, 9 or 10 on a 10 point Likert scale) when making decisions about where their relative should live and be cared for.

10.1.2 Secondary outcomes: Decisional Conflict Scale, anxiety and depression

The DECIDE manual significantly reduced carers total decisional conflict scores by over a quarter (27%) 10 weeks after completion. When compared with the control group, carers receiving the intervention felt more informed about the available options, less uncertain about the decision and clearer about their personal values. The DECIDE manual did not make carers feel significantly more supported in their decision-making although there was a trend for a positive impact on this. The DECIDE manual had no impact on carer's anxiety and depression scores which remained similar throughout study assessments.

10.1.3 Qualitative findings

Carers reported that the DECIDE manual provided an opportunity for much needed decision-making support and they valued the opportunity to talk through options with someone outside of their family. The manual facilitated carer reflection about the impact of this decision on their own lives and clarified how and where they should access further support. The DECIDE manual did not remove all barriers to decision-making for the carers interviewed; disagreements between the person with dementia or other family members trying to share decision-making often remained, despite carers who took part in the trial having greater clarity about their own decision. For some carers who reported that DECIDE did not facilitate decision-making, qualitative interviews indicated that they had decided against care home placement, but perhaps did not view this as a decision, possibly because they thought it likely they would need to review it regularly while their relative remained living at home.

10.2 Interpretation of findings

10.2.1 Outcome measures

Total Decisional Conflict Scale scores of 25 or lower have been associated with making and implementing decisions and scores that exceed 37.5 associated with delay in decision-making or implementation (O'Connor *et al.*, 1998). Results of this feasibility randomised controlled trial indicate that receiving the DECIDE intervention may increase the likelihood of making and implementing a decision; 45% (*n*=9) of participants who completed DECIDE scored 25 and under on the Decisional Conflict Scale at the 10 week follow-up assessment and 15% scored over 38 (*n*=3) while in the control group, 14% (*n*=3) of individuals scored 25 and under and 57% (n=12) scored over 38. The Decisional Conflict Scale was not developed to measure decision-making behaviour but the participant's internal conflict. While results for actual decisions made cannot be analysed statistically due to small numbers, in the intervention group, the number of carers unsure about where the person they care for should live decreased from five to two over 10 weeks, while in the control group the number increased from one to two carers. This would be a potentially relevant outcome in a future, larger trial.

A systematic review of studies that used the Decisional Conflict Scale as an outcome measure reported that the overall mean difference was -6.22 for decision aids compared to usual care. The DECIDE manual resulted in a mean difference of almost double this (-11.96) when compared to usual care at 10 weeks. The review also reported that the 'Informed' sub-scale had a mean difference across 22 studies of -7.26 (Stacey *et al.*, 2014), in this study it was -12.95. I found a clinically and statistically significant difference in decisional conflict scores between participants who did and did not receive the DECIDE manual, with a large effect size (defined as 0.8 and higher)(Cohen, 1988). I had estimated, based on a minimum clinically significant effect size of 0.4 that 100 participants in each arm would be required. In the trial, the effect size was over twice this minimum clinically significant effect size (Cohen's *d* = 0.93).

These findings however should be treated with caution as the small sample size of this trial (20 in each group) may mean that any chance finding is magnified.

The generalisability of my findings are also limited as I only recruited carers from London memory clinics and London has a different sociodemographic profile to the rest of the UK; in the 2011 Census, London had the highest proportion (92%) of people who do not provide any unpaid care for someone with an illness or disability and for every single ethnic group other than 'White British', London had the highest proportion in the UK.

The DECIDE manual did not change carers reported anxiety and depression scores, consistent with previous evidence (Stacey *et al.*, 2014). This finding is unsurprising as the intervention did not target anxiety and depression, but it is reassuring that despite increasing readiness to make this decision, anxiety and depression did not increase. Usually, individually tailored, multicomponent psychological interventions are necessary in order to have beneficial effects on these symptoms for carers (Pinquart and Sorensen, 2006; Selwood *et al.*, 2007; Brodaty and Arasaratnam, 2012; Beinart *et al.*, 2012). Hospital Anxiety and Depression Scale caseness was defined as a cut-off score of 8 or above on both the anxiety and depression sub scales (Bjelland *et al.*, 2002). Both groups therefore had fairly high anxiety levels at baseline (intervention mean = 8.65; control mean = 8.38) and 10 week follow-up assessments (intervention mean = 8.50; control mean = 8.52). Depression scores were lower for both groups throughout (baseline intervention mean = 5.85; control mean = 4.52; 10 week follow-up intervention mean = 5.85; control mean = 5.43). Whilst DECIDE may reduce decisional conflict during these placement decisions, I recognise that carers will be negotiating many aspects of caring for their relatives with dementia both in the past and in the future and that DECIDE addresses just one component of their potential carer burden at a certain point in their caregiving experience.

10.2.2 DECIDE development and delivery

I was the only 'professional' delivering the DECIDE intervention to carers therefore I could not assess any 'therapist effect'. The 'therapist effect' is a widely debated topic with variability in research outcomes being potentially due to differences in the therapist delivering an intervention (Lutz *et al.*, 2007; Anderson *et al.*, 2009; Cella *et al.*, 2011). The DECIDE manual has not yet been field tested with practitioners presenting the various options regarding place of care. This would be a next step.

People with mild cognitive impairment or dementia were included in the development of the DECIDE manual. Carers of people with dementia were offered the opportunity to have discussions about future place of care with their relative present, however only one participant did, with all others saying they would prefer to speak with me alone. This may be because they were not sure exactly what we would be discussing during completion of the DECIDE manual and had concerns about upsetting their relative or wanted to be able to think about their feelings alone.

Although the DECIDE manual significantly reduced decisional conflict, the qualitative interviews identified some barriers to decision-making that the manual did not seem to effectively help with. Carers still felt they struggled when making the decision as a family to honour everyone's wishes and sometimes there was conflict. Perhaps completing the manual with several family members together could be more helpful and this could be offered when the manual is used in future or an additional section added to the manual about how to discuss this decision together and manage conflict. There was still a lack of clarity for carers about exactly who is responsible for what in terms of their relative's care and who they should be contacting when they need advice. The findings support previous research that timing of when to make this placement decision is difficult and in reality often delayed until a crisis. Discussing viewpoints before crises arise might potentially reduce the anticipated regret and guilt

about the option chosen that is often reported (Alzheimer's Society, 2009; Livingston *et al.*, 2010).

During the development process (Chapter six) healthcare professionals felt they should let carers be proactive and initiate contact if and when they needed help. In contrast, the carers interviewed (Chapter nine) would like healthcare professionals to regularly contact them and maintain that contact. This difference in view point is a potential barrier to effective shared decision-making between the two groups and the DECIDE manual may be appropriate tool to assist in facilitating this.

10.3 Clinical implications

NICE Clinical Guidelines advocate the use of decision aids by clinicians to facilitate shared decision-making. I have created and a tested a decision-aid that reduces carer's decisional conflict which has previously been associated with delays in decision-making and decisional regret (O'Connor, 1993; O'Connor *et al.*, 1999; Walker and Dewar, 2001).

The findings from this study suggest that using the DECIDE manual in current healthcare professional practice may help to support carers making these complex, value-sensitive decisions. The findings are relevant to healthcare professionals in terms of how they facilitate conversations with carers and to healthcare commissioners responsible for resourcing NHS services for carer support.

The majority of carers who were approached agreed to take part in the study and were very willing to have discussions about where their relative with dementia may live in the future. Carers welcomed the structured nature of the decision-aid for presenting and clarifying options. Healthcare professionals are aware of the difficulty in discussing future place of care decisions with relatives due to the very emotional nature of the decision and so therefore may avoid raising this. This positive preliminary evidence that

the DECIDE manual may reduce decisional conflict suggests that professionals should be initiating structured discussions about future place of care and provides a tool to assist with this. This might help some carers initiate planning around place of care before a crisis occurs. DECIDE is a relatively simple intervention that can be printed off and used by clinicians in practice. Although I have not conducted an economic analysis, the costs of the intervention will be clinician time and printing the manual, there are no other associated costs.

My findings highlight the amount of time needed to both have these conversations and also for a decision to be reached by carers. I spent approximately 45 minutes with each carer completing the DECIDE manual and in a time pressured clinical setting such as the NHS this may not be feasible. A systematic review of barriers and facilitators to implementing shared decision-making into clinical practice concluded that time constraints were the most cited barrier in practice across many different cultural and organisational contexts (Légaré *et al.*, 2008). An ongoing challenge of healthcare decision-making is how to facilitate these often complex discussions when numerous individuals and family members are involved. Care homes may wish to consider how difficult carers find negotiating waiting lists for available places and the time pressure they are placed under to make a decision once a place becomes available. Both of these factors often force a decision on carers when in hindsight they think they may have been able to care for their relative for longer (Kraijo *et al.*, 2015).

Finally, my findings raise discussion about the length of time carers need to make and implement this place of care decision as only three carers had achieved this during the study duration. It may be that there is a need for 'watchful waiting' by clinicians when carers are making place of care decisions over a number of months as there is no right or wrong choice and there may not be an immediate demand for a decision (O'Connor *et al.*, 2003).

10.4 Methodological strengths and limitations

10.4.1 Sources of bias

Selection bias

It can be very difficult to test a decision aid in a real world setting at the appropriate time for individuals who are considering all the necessary options (Graham *et al.*, 2003). I achieved this by only recruiting carers who were in the process of making the decision being studied. I was however reliant on healthcare professionals within the memory clinics identifying eligible participants and therefore there is a chance that other appropriate carers were not included. Carers who were considering placement but did not raise it as an issue with healthcare professionals may not have been informed about the study. It is clear from my focus groups that healthcare professionals in services I recruited from were not raising this issue proactively with carers. Those who did not discuss concerns with healthcare professionals might have differed systematically in their decision-making style from those that did. Despite this, randomisation was independent therefore we can assume that the two groups studied are comparable.

Observer bias

Observer bias may be present when the predispositions of the observer or researcher impact the findings of a study. Although none of the measures collected as part of the DECIDE trial involved my personal judgement, I developed the DECIDE manual and was hoping that it would be successful in reducing carers decisional conflict. Social desirability bias refers to a respondent providing an answer which is more socially acceptable than their true attitude or behaviour in order to appear more favourable to the interviewer (Tourangeau *et al.*, 2000). Participants were aware that this was my PhD project and that I had been responsible for developing the manual therefore may have responded in a positive way to help show that it had 'worked'. Having someone

unrelated to the design of the intervention and study to deliver the DECIDE manual to carers would have been a way of avoiding this.

Blinding

The methodological difficulty of most evaluation studies is that they cannot be double-blind (Graham *et al.*, 2003) as was the case in this trial. A potential source of bias in this study is that I was not blinded to the allocation group as I was the only researcher collecting data. It was not possible to blind study participants.

Instrument bias

All outcome measures included in the feasibility trial had previously demonstrated reliability and validity. Participants were offered the opportunity to self-complete the outcome measures during all assessments of the DECIDE study as evidence suggests that there is a higher chance of participants revealing socially undesirable answers in self-completion methods in comparison to interviewer administered methods (de Leeuw, 2005; Holbrook and Krosnick, 2010).

Attrition bias

Loss to follow-up can greatly affect the strength of a trial's findings (Dumville *et al.*, 2006). One participant in the control arm did not complete all study assessments, therefore, the DECIDE trial has a loss to follow-up of only 2%.

Statistical bias

Due to the small sample size of the trial, there is the risk of Type 1 errors, a false positive, with the findings. Caution must be taken when interpreting and extrapolating from the results.

10.4.2 Study population

Only carers with sufficient English to complete the study measures were recruited. If the DECIDE manual is to be used in clinical practice, it might be appropriate to offer translated versions, although cultural adaptation may be necessary. As identified in my systematic review, carers from some minority ethnic groups felt a greater sense of responsibility to care for their relatives at home; it can be particularly challenging to find a suitable care home for a person with dementia who does not, or no longer speaks, English fluently (Kwon and Tae, 2012; Chang *et al.*, 2011). Home life for carers will be embedded in the individual's and their families' cultural context and DECIDE needs to be sensitive to this. People from minority ethnic groups present later to specialist diagnostic and therapeutic services and this may be due to feeling that it is the families responsibility to care for that individual (Mukadam, 2011). It may be that I did not recruit very many carers from minority ethnic groups as they had not yet contacted the memory services I was recruiting from. There is also evidence that minority ethnic groups are less likely to access dementia research trials (Cooper *et al.*, 2010). Evidence from a small study found that encouraging South Asian UK minority groups to make an appointment with a South Asian worker to discuss memory may increase help-seeking for a memory concern (Mukadam *et al.*, 2015).

I did not collect data about the carers relatives with dementia, for instance the severity or type of their dementia and these factors may have an influence on carer's decision-making. Over 70% of the carer sample was female however, a recent report by Alzheimer's Disease International (2015) found that globally two-thirds of family carers are female.

10.4.3 Study design

I used a rigorous and replicable development process in creating the DECIDE manual based upon the Medical Research Council developing complex interventions guidelines (2008), the International Patient Decision Aid Standards criteria (Elwyn *et al.*, 2006) and

the Ottawa Decision Support Framework. People with dementia, their family carers and healthcare professionals were all consulted about the content and layout of the DECIDE manual, which I have developed iteratively, incorporating their feedback.

Using a mixed methods approach for the feasibility randomised controlled trial allowed exploration of the impact of the DECIDE manual and helps to understand the context in which carers are making decisions and the factors that may help or hinder this. A strength of this study is that I outlined clear criteria for success for my feasibility trial. I controlled for usual care and detailed what that comprises. A number of other studies have also measured carer knowledge of the content of the decision aid and this would have been an interesting additional secondary outcome (Stacey *et al.*, 2014). The Decisional Conflict Scale has been used in a number of clinical settings however it is not an outcome measure routinely collected in clinical practice with carers of people with dementia. It is a rather lengthy tool to administer and complete (16 items). As an alternative, the 4 item SURE checklist was developed specifically to screen for decisional conflict associated with a Decisional Conflict Score greater than 37.5 out of 100 (Legare *et al.*, 2010). SURE shows adequate psychometric properties in a primary care population with a low prevalence of clinically significant decisional conflict when compared with the Decisional Conflict Scale (Ferron Parayre *et al.*, 2014). One way that I could have reduced the time spent by carers completing the outcome measures of the trial, SURE may have been a suitable alternative to the Decisional Conflict Scale.

10.4.4 Use of decision aids in dementia

Little is also known about the amount of detail needed within the decision aid in order for it to have a positive effect on decision-making (Stacey *et al.*, 2014). With further use of the DECIDE manual in clinical practice, we may be able to gain further insight about whether more or less detail is needed. There is also little evidence about how many times individuals refer to and use decision aids in order to make a decision. I did not ask carers if they read or used the DECIDE manual additional times other than during

completion with myself. It may have been that those carers who repeatedly referred to the information discussed had greater reduction in decisional conflict.

There is some difficulty in providing information about future place of care options for people with dementia via a decision aid because dementia is an unpredictable illness, the risks of continuing to live in one's own home as dementia progresses are often impossible to accurately quantify and in most cases decisions balancing risk against desire for independence are being made by proxy; it is probably harder to make a decision that exposes another person to risk than to accept risk oneself. With a topic such as this, relying on knowledge and experience of the individual delivering it to carers is a key factor, without which it may not be as effective. The IPDAS criteria suggest field testing of the decision aid with practitioners who will ultimately be delivering it in clinical practice. Whilst I was unable to do this as part of the PhD, I would like to, in a future project, work with clinicians within the memory services who feel they are best placed to deliver the DECIDE manual to gain more understanding of its use in practice.

10.5 Alternative study design

The DECIDE study is just one way to explore the impact of a decision-aid for carers of people with dementia. There are several different ways to deliver decision aids. A longer term follow-up of carers who had used the manual may provide data about how carers evaluated their decisions some years later; I have measured decisional conflict, but I have not attempted to measure quality of the decision. This is a complex issue and perhaps decisional quality is best determined by the people who made them some time after the event. A future, pragmatic trial of DECIDE to evaluate its effectiveness in reducing decisional conflict in clinical practice should also include an analysis of cost-effectiveness.

An alternative study design could have also included, where possible, people with dementia or offered to complete the DECIDE manual with multiple family members if carers felt this would have been useful. This may go some way to address the continued barrier carers reported of trying to make this decision with the wider family unit.

The DECIDE manual is designed for use by a carer and healthcare professional whose knowledge adds to the resource, collaboratively. Although we would not ask carers to complete the DECIDE manual alone, perhaps being able to refer to this online would be helpful and uploading an electronic copy to any necessary electronic medical records that could be shared amongst healthcare professionals (with the carers permission) would assist in facilitating this conversation. I carried out the intervention face-to-face with carers; online platforms such as Skype might have been a viable and potentially cheaper alternative. There is a growing body of evidence that video consultations in clinical practice are feasible and of benefit (Armfield *et al.*, 2015). Greenhalgh *et al.* (2016) are currently exploring the advantages and limitations of virtual online consultations in the VOCAL Study.

10.6 International Patient Decision Aid Standards (IPDAS) Checklist

Following the completion of the feasibility randomised controlled trial and feedback from carers in the intervention arm, the DECIDE manual (version three) was created (Appendix 28). The DECIDE manual has been developed, where possible, in line with the IPDAS criteria (Elwyn *et al.*, 2006). In Appendix 29, I have evaluated the DECIDE manual (version three) against these criteria.

The IPDAS criteria recommend that a decision aid should be written at grade 8 level (13-14 years old) or less. The DECIDE manual is currently written at a grade 9 (14-15 years old) equivalent level according to a readability score (The SMOG Index at www.ReadabilityFormulas.com). I have simplified the language where possible. I

recruited individuals with a range of educational backgrounds (8 to 23 years of full-time education) and none of the participants had difficulties understanding and completing the manual.

I have created a one page supporting document for the decision aid detailing more about the development process and information to meet other criteria in the IPDAS checklist. This information, which includes references to evidence used, the quality of this and sources of funding can be made available to carers if they request it (Appendix 30).

Chapter 11 Future directions

In this chapter, I will discuss the implementation plan for the DECIDE study and potential directions for future research.

11.1 Implementation plan

In line with the MRC guidance (2008) (see Figure 1), the next stage of the development process is to consider implementation of the intervention into clinical practice. Further testing of the DECIDE manual in a randomised controlled trial with a sufficiently powered sample size is needed to fully assess its effectiveness and the generalizability of the findings. To inform future research to test the DECIDE manual, I consider below how it might be implemented in future.

Elwyn *et al.* (2013) conducted a systematic review of the implementation of patient decision support interventions into clinical practice. They concluded that providing training and skills development for healthcare professionals who will be delivering the decision aid facilitated implementation. Identification of a champion for the implementation, especially an individual in a leadership position was also a facilitator. An issue identified as a barrier to implementation was indifference from healthcare professionals who felt that they lacked the time to incorporate decision aids into their practice and that it was not part of their role. In considering the implementation of DECIDE, it is important to ensure that the individual healthcare professionals' who will be delivering DECIDE have the confidence and skills in being able to discuss options and potentially emotive topics with relatives (Légaré *et al.*, 2010). It is also important to consider factors such as the service level support for the time for clinicians to facilitate these often complex conversations. In a time and resource pressured environment like the NHS this can often be difficult. Inclusion of shared decision-making within national guidance may go some ways to increase practitioner's awareness of the need for interventions such as DECIDE. Initial dissemination of the manual could take a 'Train

the Trainers' format which has been used in a number of settings including in delivering end of life care training to care home staff (Mayrhofer *et al.*, 2016). This method involves training one or two members of staff who then in turn go on and train other members of staff within their service, cascading the information down.

11.2 Future research direction

11.2.1 Who should deliver DECIDE?

In the DECIDE feasibility trial, I was the only individual responsible for delivering the intervention, as a result, it has not been field tested being delivered by other people. A future research project would need to identify appropriate personnel to do so and assess fidelity to the manual so as to investigate any 'therapist effect' further. In such a study, if randomising at the clinician level, in order to avoid cluster contamination of the findings, we would need to consider the effects of clustering on the necessary increase to sample size calculation. I trialled the DECIDE manual in memory services but perhaps using this resource in old age hospital wards with carers of people with dementia may be useful, as many people with dementia who move to a care home do so directly after a hospitalisation. Dementia significantly increases the length of admission to hospital, often because of issues with the discharge process (Mukadam and Sampson, 2011) and it would be interesting to establish if the DECIDE manual had any impact on that outcome. Sampson *et al.* (2011) found that it was difficult to have Advanced Care Plan discussions with carers in hospital when no private room was available and some carers preferred to remain at the patient's bed side. Finding an appropriate space to discuss sensitive matters would need to be considered if delivered in inpatient settings. Alternatively, Social Services may be an appropriate setting to deliver such an intervention as they are called upon to perform tasks such as access to resources and creation of care plans throughout the dementia illness (Kaplan and Berkman, 2011), often in peoples own homes.

The DECIDE manual takes approximately 30-45 minutes to deliver, therefore, healthcare professionals within the NHS may struggle to be able to implement it without additional funding for that time. Delivery by staff without formal clinical training (such as assistant psychologists within the NHS) or third sector staff (for example Alzheimer's Society research network volunteers) could potentially be more cost-effective than delivery by highly trained clinical practitioners, and effective if there is sufficient training, liaison and supervision by clinical staff. The use of psychology graduates without clinical training or non-clinical community workers trained and supervised by clinical psychologists and old age psychiatry clinicians has proved an effective way of delivering a carer coping strategy intervention (Livingston *et al.*, 2013) and dementia care coordination intervention (Samus *et al.*, 2014).

'Peer educators' have effectively delivered a falls prevention education for community dwelling older people (Khong *et al.*, 2015). Systematic reviews have concluded volunteer mentoring for carers of people with dementia was not efficacious (Smith and Greenwood, 2014) and decision coaches who are independent of the health care team were less effective when their services were not coordinated with the practitioner's role (Charlesworth *et al.*, 2008; Stacey *et al.*, 2012). Given this mixed evidence, considering the feasibility of peer carers delivering the DECIDE manual to other carers will need exploring further.

11.2.2 Tailoring DECIDE for specific groups

Increasingly sophisticated technology platforms potentially enable manualised resources to be tailored to the specific needs of a carer. This could perhaps include tailoring the DECIDE intervention to the specific needs of spousal carers, who might also be considering whether to move together to more supported accommodation with their relative or to live apart. Carers from minority cultural and ethnic backgrounds might also find an intervention more tailored to their cultural background helpful given the impact of cultural issues on the emotional strain of making the decision (Chang *et*

al., 2011; Kwon and Tae, 2012; Caldwell *et al.*, 2014). Development work would be needed to determine whether and what type of intervention might be helpful in different ethnic groups. Delivery of interventions by workers from the same ethnic background has previously been shown to be effective (Mukadam *et al.*, 2015) and could be considered in this context taking into account the practicalities and ethics of this.

An additional consideration for future research is the impact of the type of dementia an individual has on carer's decision-making. Individuals with Alzheimer's disease may experience a slow progression in their disease over many years and changes in the amount of care relatives are providing may be gradual. In contrast, individuals with frontotemporal dementia may experience more behavioural disturbance which may have a greater impact on the decision carer makes about future place of care. In the DECIDE study I did not collect data about the type of dementia carers' relatives had but would do so in a future trial.

Finally, in clinical practice, there are a number of individuals with dementia who have no relatives to act as decision makers for them. The DECIDE manual might potentially be helpful to Independent Mental Capacity Advocates (Act, 2005) charged with representing the wishes of a person without dementia who lacked capacity and had no family member or friend to represent them in decisions about place of care.

11.2.3 How much does DECIDE cost?

A full examination of cost-effectiveness could potentially justify funding additional time for NHS practitioners to implement DECIDE. A systematic review on assessing the potential financial savings of decision aids (Walsh *et al.*, 2014) found only seven studies that provided such data and authors concluded that there was insufficient evidence to be confident that implementation of decision support interventions lead to system-wide savings. They call for better quality evidence to truly assess the impact. I did not

carry out an economic analysis of the DECIDE manual and this would be valuable evidence to have alongside the clinical impact of the intervention. There may be economic benefits of such an intervention, for example, in facilitating discharge from hospital to place of care or providing information about options that can keep people living in their own homes for longer. Conversely, DECIDE may facilitate more people making the decision to move their relative to a care home which may cost more money. Examination of the impact of the DECIDE manual on future service use by carers and people with dementia would be necessary. An economic analysis could build the case to support the implementation of DECIDE.

11.2.4 How should we deliver DECIDE?

With the rapid advances in technology, it is important to consider how to utilise this in the delivery of the DECIDE intervention. Electronic care coordination information systems are being increasingly used within the NHS and Social Services in order to share patient information. If I provided an electronic version of the DECIDE manual this would enable the information carers included when completing it to be shared across agencies, with the carer's permission. The manual could be attached to patients' medical notes and available to be completed with an appropriate individual.

There are an increasing number of mobile applications being developed for both physical and mental health conditions, for example over a hundred self-help apps are available for people with depression (Huguet *et al.*, 2016). Mobile applications for people with dementia, such as to provide reminders or to promote exercise, are being increasingly developed and tested for their usability (Zapata *et al.*, 2015). Difficulties that older adults may experience when using such technology need to be considered, with health applications tailored to the users' needs (Zapata *et al.*, 2015; Span *et al.*, 2015). Working with developers and users in exploring the usability of the DECIDE manual in such a format would be a potential future research study.

Transitions in place of care are not just a dementia specific issue, therefore resources such as the DECIDE manual could be tailored to various other populations, for example people with Learning Disabilities and facilitate conversations between healthcare professionals, patients and their families. A future research direction may be to provide the DECIDE manual as a 'template' to be used with other patient groups and assess its impact. This may provide valuable information about what components of the intervention are most effective when making place of care decisions.

Chapter 12 Conclusions

In principle, decision support interventions should respect a patient's individual values, personal resources and capacity for self-determination. When individuals are no longer able to participate in decision-making, supporting proxy decision-making, which is reported as difficult, is necessary.

The primary aim of this study was to develop and test the feasibility and acceptability of a decision aid to enable family carers of people with dementia to make decisions about the future place of residence of the person for whom they care. I have used a rigorous and replicable process, in collaboration with people with dementia, their family carers and healthcare professionals, to develop the DECIDE manual.

With the assistance of the clinical teams, I was able to successfully recruit carers of people with dementia who were in the process of making decisions about where their relative lives in the future; study retention rates were high. All participants felt the DECIDE manual was useful and relevant. When compared to the control group, the DECIDE manual significantly reduced decisional conflict for carers 10 weeks after completing it. The manual also made carers feel significantly more informed about the available options, reduced their uncertainty about the decision and helped clarify their personal values. My qualitative evaluation indicated that while DECIDE was considered helpful, carers still faced barriers in making these difficult decisions, with family complexities and challenges involving the person with dementia highlighted by participants as well as ongoing challenges of navigating numerous services.

This small trial showed that carers benefited from the DECIDE manual and would welcome it as part of their post-diagnostic support. A rational next step would be to test the effectiveness and cost-effectiveness of this decision support intervention in an appropriate, ‘real world’ setting, by the appropriate individuals. Further exploration of how we can address the ongoing challenges carers face in making this decision, in

particular, managing multiple family members' disagreements, would also add to both the research literature and clinical practice.

Appendix 2: IPDAS criteria checklist

International Patient Decision Aid Standards Collaboration

Criteria Checklist

This checklist was published in the following article:

Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, Thomson R, Barratt A, Barry M, Bernstein S, Butow P, Clarke A, Entwistle V, Feldman-Stewart, D, Holmes-Rovner M, Llewellyn-Thomas H, Moumjid N, Mulley A, Ruland C, Sepucha K, Sykes A, Whelan T. **Developing a quality criteria framework for patient decision aids: online international Delphi consensus process.** *BMJ* 2006;333:417. [http://www.bmj.com/cgi/content/full/333/7565/417]

I. Content

Provide **information** about options in sufficient detail for decision making?

	Yes	No
Does the patient decision aid describe the health condition?		
Does the patient decision aid list the options?		
Does the patient decision aid list the options of doing nothing?		
Does the patient decision aid describe the natural course without options?		
Does the patient decision aid describe procedures?		
Does the patient decision aid describe positive features [benefits]?		
Does the patient decision aid describe negative features of options [harms / side effects / disadvantages]?		
Does the patient decision aid include chances of positive / negative outcomes?		
Does the patient decision aid describe what test is designed to measure?		
Does the patient decision aid include chances of true positive, true negative, false positive, false negative test results?		
Does the patient decision aid describe possible next steps based on test result?		
Does the patient decision aid include chances the disease is found with / without screening?		
Does the patient decision aid describe detection / treatment that would never have caused problems if one was not screened?		

Present **probabilities** of outcomes in an unbiased and understandable way?

	Yes	No
Does the patient decision aid use event rates specifying the population and time period?		
Does the patient decision aid compare outcome probabilities using the same denominator?		
Does the patient decision aid compare outcome probabilities using the time period?		
Does the patient decision aid compare outcome probabilities using the scale?		
Does the patient decision aid describe uncertainty around probabilities [words, numbers, diagrams]?		
Does the patient decision aid allow the patient to select a way of viewing probabilities based on their own situation [e.g. age]		
Does the patient decision aid place probabilities in context of other events?		
Does the patient decision aid use both positive and negative frames [e.g. showing both survival and death rates]		

1

Include methods for clarifying and expressing patients' values?

	Yes	No
Does the patient decision aid describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional and social effects?		
Does the patient decision aid ask patients to consider which positive and negative features matter most?		
Does the patient decision aid suggest ways for patients to share what matters most with others?		

Include structured guidance in deliberation and communication?

Does the patient decision aid...	Yes	No
Does the patient decision aid provide steps to make a decision?		
Does the patient decision aid suggest ways to talk about the decision with a health professional?		
Does the patient decision aid include tools [worksheet, question list] to discuss options with others		

II. **Development Process**

Present information in a balanced manner?

	Yes	No
Is the patient decision aid able to compare positive / negative features of options?		
Does the patient decision aid show negative / positive features with equal detail [fonts, order, display if statistics]?		

Have a systematic development process?

	Yes	No
Does the patient decision aid include developers' credentials / qualifications?		
Does the patient decision aid find out what users [patients, practitioners] need to discuss options?		
Does the patient decision aid have a peer review by patient / professional experts not involved in development and field testing?		
Has the patient decision aid been field tested with users patients facing the decision?		
Has the patient decision aid been field tested with practitioners presenting options?		
The field tests with users [patients, practitioners] show the patient decision aid is acceptable?		
The field tests with users [patients, practitioners] show the patient decision aid is balanced for undecided patients?		
The field tests with users [patients, practitioners] show the patient decision aid is understood by those with limited reading skills?		

Use up to date scientific evidence that is cited in a reference section or technical document?

	Yes	No
Does the patient decision aid provide references to evidence used?		
Does the patient decision aid report steps to find, appraise, summarise evidence?		
Does the patient decision aid report date of last update?		
Does the patient decision aid report how often patient decision aid id updated?		
Does the patient decision aid describe quality of scientific evidence [including lack of evidence]?		
Does the patient decision aid use evidence from studies of patients similar to those of target audience?		

Disclose conflicts of interest?

	Yes	No
Does the patient decision aid report source of funding to develop and distribute the patient decision aid?		
Does the patient decision aid report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid?		

Use plain language?

	Yes	No
Is the patient decision aid written at a level that can be understood by the majority of patients in the target group?		
Is the patient decision aid written at a grade 9 or equivalent level or less according to readability score [SMOG or FRY]?		
Does the patient decision aid provide ways to help patients understand information other than reading [audio, video, in-person discussion]?		

Meet additional criteria if the patient decision aid is internet based?

	Yes	No
Does the patient decision aid provide a step-by step way to move through the web pages?		
Does the patient decision aid allow patients to search for key words?		
Does the patient decision aid provide feedback on personal health information that is entered into the patient decision aid?		
Does the patient decision aid provide security for personal health information entered into the decision aid?		
Does the patient decision aid make it easy for patients to return to the decision aid after linking to other web pages?		
Does the patient decision aid permit printing as a single document?		

3

Meet additional criteria if **stories** are used in the patient decision aid?

	Yes	No
Does the patient decision aid use stories that represent a range of positive and negative experiences?		
Does the patient decision aid report if there was a financial or other reason why patients decided to share their story?		
Does the patient decision aid state in an accessible document that the patient gave informed consent to use their stories?		

III. **Effectiveness**: Does the patient decision aid ensure decision making is informed and values based?

Decision process leading to **decision quality**...

	Yes	No
The patient decision aid helps patients to recognise a decision needs to be made?		
The patient decision aid helps patients to know options and their features?		
The patient decision aid helps patients to understand that values affect decision?		
The patient decision aid helps patients to be clear about option features that matter most?		
The patient decision aid helps patients to discuss values with their practitioner?		
The patient decision aid helps patients to become involved in preferred ways?		

A pdf version of this checklist is available for download on http://www.decisionlaboratory.com

Note: Based on this IPDAS checklist, a new instrument has been developed to assess the quality of decision support interventions – IPDASi. For details see: http://www.ipdasi.org/ or contact: IPDAS@Cardiff.ac.uk

Appendix 3: Decision aid development publication: Lord *et al*. (2016)

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BMC Geriatrics

RESEARCH ARTICLE Open Access

How people with dementia and their families decide about moving to a care home and support their needs: development of a decision aid, a qualitative study

Kathryn Lord*, Gill Livingston, Sarah Robertson and Claudia Cooper

Abstract

Background: People with dementia and their relatives find decisions about the person with dementia living in a care home difficult.

Methods: We interviewed 20 people with dementia or family carers around the time of this decision in order to design a decision-aid.

Results: Decision-makers balanced the competing priorities of remaining somewhere familiar, family's wish they remain at home, reduction of risk and effects on carer's and person with dementia's physical health. The person with dementia frequently resented their lack of autonomy as decisions about care home moves were made after insight and judgment were impaired. Family consultation usually helped carers but sometimes exacerbated tensions. Direct professional support was appreciated where it was available. There is a need for healthcare professionals to facilitate these conversations around decision-making and to include more than signposting to other organisations.

Conclusions: There is a need for a healthcare professional facilitated decision-aid. This should detail what might change for the person with dementia and their carer, possible resources and alternatives and assist in facilitating discussion with the wider family; further research will develop and test a tool to facilitate decision making about place of care needs.

Keywords: Decision-making, Dementia, Carers, Place of care, Care home

Background

People with dementia often need increased care at home or are required to move to live with or nearer relatives or to a 24 h care facility as the illness progresses due to increasing dependency, safety concerns, neuropsychiatric symptoms or family members becoming increasingly frail and unable to care [1]. The decision to move is often difficult and stressful [2, 3], especially as the person with dementia and their family may have never thought that they would live in a care home and there may be disagreement about the need to do so coupled with concerns that the person with dementia may never learn to navigate their new surroundings.

People with dementia may have expressed their wishes about future place of care through advanced statements or family discussions at an earlier time when more able to consider and express their preferences as many people with mild or moderate dementia can participate in decision-making to some extent [4]. In general, when they are well most people do not plan that they or their relatives will move into a care home [3]. Most, who can no longer manage living in their current circumstances, rely on family carers to negotiate choices and make

* Correspondence: k.lord@ucl.ac.uk
Division of Psychiatry, University College London (UCL), 6th Floor Maple House, London W1T 7NF, UK

healthcare decisions on their behalf to some extent. A recent systematic review found that family carers find proxy decision-making, especially around place of care, challenging and distressing, especially when decisions are made against the wishes of the care recipient and support from healthcare professionals is lacking [5].

There is limited evidence about how people with dementia and carers make this important and difficult decision and what might reduce their distress. This qualitative study was part of the DECIDE project to create and test a resource to help people with dementia and their family carers make decisions about living arrangements and future place of care. We interviewed both people with dementia and their family carers about how they made these decisions for, to our knowledge, the first time in a published study. We sought to understand the decision-making process, the needs and difficulties they encountered and how these may be overcome.

Methods

This study was approved by National Research Ethics Service Committee London – Bloomsbury (January 2014; REC Reference: 14/LO/0012).

Recruitment

Memory clinic clinicians identified and approached potential participants and they were given or sent information sheets. They were approached by the researcher (KL) after a minimum of 24 h and if they were interested they met her, discussed the study and gave written informed consent. If the clinicians or researchers at any point judged any individual lacked capacity as defined and measured by the Mental Capacity Act (2005) [6], they were excluded from participation in the study. Recruitment ceased when it was judged that data saturation was reached; this is when the inclusion of an additional interview did not significantly add to the knowledge that had been gained [7]. Sample size recommendations from the Ottawa guidelines of developing and evaluating patient decision aids were also considered [8].

Sample

Participants were from memory clinics in inner and outer London and were people with a clinical diagnosis of dementia or their family carers. Eligible carer participants were the current, unpaid, main family or friend carer. In order to encompass a range of views and maximize the validity of our findings we sought to interview a demographically diverse range of people with dementia and carers who were currently in the process of making a decision about, or had recently made the decision about, future place of care or residence. We therefore recruited purposively to include those who lived in inner cities and suburban areas, of either sex, a range of age groups, relationships to the person with dementia, ethnicities and severity of dementia.

We excluded participants who spoke insufficient English to participate in the interview or who did not have the capacity to consent to the interview.

Interview

All participants were offered the opportunity to be interviewed either alone or, in the case of a person with dementia and carer dyads, to be interviewed together by KL. One of the people with dementia and their family carer were interviewed together. All other interviews were conducted individually and lasted a maximum of one hour.

We conducted semi-structured interviews in participants' homes, using a topic guide. The topic guide was developed by the authors, based on the findings from the CHOICE study that reported which decisions family carers found difficult to make for people with dementia who did not have the capacity to make their own decisions and facilitators of and barriers to such decisions [3]. As the CHOICE interviews were limited to family members of people with dementia, we then further consulted clinicians from memory clinics (Old Age Psychiatrists and Clinical Psychologists) and dementia researchers to ensure the content of the interviews included any further relevant topics

Making the decision

We asked people with dementia and carers about current living arrangements; we asked them to discuss they had any concerns about where the person with dementia lives (and prompted them to consider loneliness, distance from family, safety and the care available). We explored any differing views within the family and between the family and the person with dementia. We also asked participants to detail the extent to which the participant had been involved in making decisions, and whether they experienced any difficulties; whether they had felt supported and by whom (with prompts about family and healthcare professionals). We asked whether they had talked to anyone about this decision and if so whether this was helpful.

Development of a decision aid

We explored with participants what might help make this decision about future place of care and whether there was any information they wish they had had. We then prompted them by showing them a previous information leaflet we had developed based on what had helped family carers called "Deciding about a care home" and asked for any comments and improvements to these in terms of form and content and specifically when and how they would want to use this information.

Analysis

We digitally audio recorded all interviews and transcribed them verbatim, removing all identifying information from transcripts prior to analysis. We used the qualitative research software Nvivo 9 to code, manage and analyse all data. Two researchers (KL and SR) thematically coded all data independently to ensure reliability, generating a coding frame from initial interviews using a thematic content analytic approach. Disagreements between the researchers were resolved through discussion with each other and a consensus was reached. Participants were offered the opportunity to make any alterations to their own transcripts so that we knew it was a true record of what they intended to say and they were able to elaborate if they wished as a method of quality control and validation. In total only two participants took the opportunity to review their transcripts and made no changes to what they had said.

Results

Demographics

We interviewed 20 participants; seven with dementia, four of whom had a family carer also participate and an additional nine other family carers. The socio-demographic details of both carers and people with dementia are detailed in Table 1. The main themes identified are detailed below. One of the participants with dementia had recently moved to a care home due to safety concerns and another had moved out of a care home to their relative's home in a different part of the country. All of the other five people with dementia interviewed were currently living at home. The nine carers who were interviewed without participation of their relative all had relatives with dementia who were living at home and were considering their options about future place of care.

Table 1 Participant characteristics

		Carers (n = 13)	People with dementia (n = 7)
Sex	Male	4	5
	Female	9	2
Age (years)	Range	32-85	71-87
	Mean	59	79
Relationship to person with dementia	Spouse or Partner	5	-
	Child	7	-
	Niece/Nephew	1	-
Living situation	Alone	2	2
	With partner	10	1
	With other relatives	1	3
	In Care home	-	1
Ethnicity	White British	11	6
	Asian	2	1
Current living environment	Flat/House	13	6
	Residential care home	-	1

Who makes the decision?

People with dementia sometimes felt, and resented, that they were not supported to participate in decision-making:

> *'I feel it's rather humiliating frankly to be treated as incompetent, unable to make my own decisions really'; 'I feel rather that I've sort of been taken over a bit and they do my thinking for me and I don't really like that very much actually' [Man with dementia living in a care home; 05]*

There were instances in which people with dementia felt that a change in their living situation was a forced decision over which they had no control or influence. One participant did not think that the person making the decision had the right to do so:

> *'Well I was, quite honestly I was forced into it'; 'The thing is that I would like to perhaps be given some option' [referring to son moving him to a care home] [Man with dementia in own home; 04]*

> *'I don't really feel I've given him the rights' [referring to care home manager getting involved in decision about where to live] [Man with dementia living in a care home; 05]*

In other cases, people with dementia and their carers felt the decision making process had been shared:

> *'Well we all sort of sat around, the three of us [person with dementia and two children] trying to find out where's the best sort of nursing home' [Woman with dementia in own home; 08]*

Carers recognized that they were taking over decision making and sometimes found this change of role difficult or overwhelming. They often acknowledged excluding the person with dementia from the process because they lacked insight into the problems necessitating a move:

> *'I'm doing everything what my husband was doing before' [Wife of person with dementia; 015]*

> *'My whole identity was caring for them' [Daughter of person with dementia; 06]*

'He doesn't want to go anywhere' [Wife of person with dementia; 015]

None of the people with dementia or their family carers described being able to refer to advance statements or written recording of the views of the person with dementia at a time when they did not have such a severe dementia.

The wider family

Where carers were making surrogate decisions, such decision-making was often shared with or discussed with the wider family. Moves affected other family members, especially where they were moving from a home shared with their spouse to a care home, or where moves were over longer geographical distances. Sometimes family members were moving to be nearer the person with dementia, other times the person with dementia was moving nearer to their relatives. This was often a difficult decision to make as it ultimately resulted in someone having to leave their home and local area, thus impacting on their social contact outside their immediate family.

'The main reason really for wanting to keep her up there [north England] as opposed to bringing her down here [London] to go to a nursing home down here was because of her friends' [Daughter of person with dementia; 07]

People with dementia and their families were concerned about isolation of the person with dementia. Sometimes carers were torn between the emotional and practical needs of the person with dementia, their own needs and other family members. One carer excluded the person with dementia to try to protect their feelings:

'My father went to pieces when she went into respite [mother with dementia]. This is really important info because that totally changed my view about what could happen to my mother. It made it very clear that if he remained as aware as he is, they couldn't be separated' [Daughter of father with dementia; 06]

'The big problem has occurred, as I knew it would, that I don't see anybody' [Woman with dementia in own home; 08]

Carers reported consulting family and friends about the decision to move their relative. Some found this helpful whilst others felt it created tension where views differed:

'We're both honest with each other and it's such a help, I don't feel I've got to hold back or that I'm going to upset her [when talking to another carer of a person with dementia]' [Wife of person with dementia; 012]

'When I think about it I think there are areas that are still a bit taboo between us, maybe we're protecting each other' [Wife of person with dementia; 012]

Familiar environment

All carers expressed a desire to maintain the person with dementia living in their own home and caring for them there where possible as they recognized familiarity of the environment and preservation of daily routine were important:

'Well I don't think either of us will move from here because we've been here so long and we like it' [Husband of person with dementia; 011]

Proximity to local amenities such as public transport and shops was seen as an important factor in maintaining independence.

The people with dementia valued remaining at home highly, especially as they often lacked insight or did not agree with reasons behind a move:

'I have suggested these things to him, that a carer might be satisfactory... well he doesn't like it... yea because I think it usurped his position' [Man with dementia in own home; 04]

Individuals with insight into their dementia often raised the discussion around the need for additional care or moving to a different care setting and expressed feelings of guilt around having the illness.

'He feels very guilty anyway... I don't want him to feel that it's [the dementia] going to blight my life'. [Wife of person with dementia; 012]

Safety

Safety concerns about falls or unsafe use of gas or electric kitchen devices, coupled with accessibility issues were the most commonly reported problems that triggered the decision making process for both carers and people with dementia:

'I think we should be in a flat... having things on one level will help,'I'm keen to be somewhere where we're not so dependent on a car. So nearer transport, nearer shops' [Wife of person with dementia; 012]

'I'd like to be sort of more truthful about it you know, not try to kid myself, but there are difficulties. I mean I'd need quite a lot of help I think... the trouble is you

see, nobody could be on 24 hours [when discussing carers coming to own home]' 'I really think I need to be monitored really' [Man with dementia in care home; 05]

In some cases the person with dementia accepted that the carer had concerns and, as they trusted the carer's view, they also accepted this as a reason to move:

'He [the carer] was very much, very keen I should get into somewhere so that I couldn't fall over' [Man with dementia in care home; 05]

Physical health

Participants discussed no longer being able to manage at home due to physical health problems. These were unrelated to the dementia but the complexity of problems made solving them difficult:

'My brother was taking her [home] and realized there was just no way he could leave her at home, she was just in no state for that [due to pain]' [Daughter of person with dementia; 07]

'It got very tough because she couldn't get into the bath due to knee, had to be strip washed' 'It's urgent because she's falling over' [Daughter of person with dementia; 06]

Participants were aware that adjustments to their current environment may enable them to stay at home longer but not all were sure how to make these adjustments and if there were services available to help:

'We don't know who to contact, we are completely lost' [Wife of person with dementia; 03]

'I still feel that I don't know all the questions to ask...I mean who gets involved, is it Social Service, who is it? And how does that begin?' [Wife of person with dementia; 012]

Carer health issues

Several participants, all from the spousal couples interviewed, raised concerns about the carer's health impacting on their ability to provide care in the future:

'I am concerned about [wife's] health... I do worry that we're both losing it' [Man with dementia in own home; 013]

'That is something that worries me, if I get worse, who is going to look after him? That's my main worry' [Wife of person with dementia; 015]

'We've also got to face the fact that we both might need care' [Wife of person with dementia; 012]

Uncertainty about the future

A central theme throughout the interviews was the knowledge that dementia progresses but uncertainty about the specific course of the illness:

'We're coping pretty well at the moment but you know in years to come it could, you know it will probably get worse' [Husband of person with dementia; 011]

'It is one of those things that I should be thinking about more and making more plans about [wife with dementias future living arrangements]' [Husband of person with dementia; 014]

'I want him to stay here, I want to do as much as I can but I really don't know what the futures like you know, I have no idea' [Wife of person with dementia; 015]

Navigating health and social care

Many participants reported being unsure which health-care professional or agency they should or could talk to, which services they were entitled to or whether services existed:

'But we don't know who to contact, we are completely lost' [Wife of person with dementia; 03]

Some felt excluded by inclusion criteria of memory services:

'If you are not on medication you are instantaneously discharged from the memory service.... So you are saying the whole service is utterly and totally determined by a pill? And it's not just that that's absurd, it's actually very upsetting, it's personally, I can't describe this feeling of exclusion' [Daughter of person with dementia; 06]

Lack of support and planning for a crisis from health-care professionals was highlighted:

'One of the problems within the whole decision making process is firstly is it's very unsupported, but secondly there was no plan b, there was no contingency for a crisis' [Daughter of person with dementia; 06]

Nearly all carers and people with dementia expressed concerns regarding how services and care were to be paid for both now and in the future which ultimately impacted on decisions that were made when thinking about place of care:

'It was a sense of this can't carry on and they shouldn't be bearing the cost of care because they don't have much savings left and the house is the asset and I don't know what's available' [Daughter of person with dementia; 06]

'Well one thing which I find rather, is that it's quite expensive, I'm paying £1000 a week' [for respite accommodation in a care home]... there's a limit to the amount I could do that' [Man with dementia living in a care home; 05]

Previous experiences, both positive and negative, with other family members with dementia who moved to a care home influenced carers and people with dementia interviewed. Media portrayal of care homes also impacted decisions not to use a care home:

'What I hear every time on the television, what I read and you know, no, no...we have been married over 50 years and I would hate to put him in a place where he's not well looked after' [Wife of person with dementia; 015]

Development of a decision aid

Participants responded positively to the idea of a decision aid focused on future place of care:

'It's probably useful to know that the kind of, what you are thinking yourself is actually the way it is, that's the way people think, other people, and that's comforting I think' [Daughter of person with dementia; 07]

What should be included in a decision aid?

Participants wanted discussions about what services are available at home to be included in a decision aid. In addition, information about changes that may occur for the person with dementia or their carers that may ultimately impact place of care decision-making was sought:

'The only thing that I would like to have a bit more of is more information about what help is available at home' [Wife of person with dementia; 012]

'Probably more of a discussion about the ways in which circumstances could change, how they might change for the carer who's own health or something may be deteriorating' [Husband of person with dementia; 014]

In terms of decision-making about place of care, both people with dementia and carers highlighted the importance that a move to a care home is not the only option available and should not be the sole focus of the information given and sufficient details of alternatives should be provided:

'Why is it so much about care homes? Why not have carers living in? ... Most people I've come across, ok they find it difficult having a carer in their home but it's still better than being in a care home' [Daughter of person with dementia; 07]

Information about how and where to access details about other organisations that may provide support or information about finance or care homes was seen as an important addition to a decision aid. The list of contact details of available resources for carers and people with dementia such as Age UK and the Alzheimer's Society was well received and provided information participants had not previously had:

'Oh how wonderful... Oh yes, excellent, some of these I haven't heard of' [Wife of person with dementia; 012]

Although these were seen as important, many felt that simply the name and contact information about these organisations was not sufficient and details about what exactly these agencies do would be most welcomed:

'It doesn't tell you what the various organisations, what the resources have to offer... I think you would do better to have a very small number and describe more carefully what they do' [Husband of person with dementia; 014]

How should a decision aid be delivered?

Participants discussed how the resource could be delivered and the importance of human interaction and support was evident given the complicated nature of this decision-making process:

'That moment of being, feeling really supported, that's why I wonder when you talk about a resource, for me the most important resource are humans... Sitting next to somebody filling in a form together was, I can't tell you how supportive that was' [Daughter of a person with dementia; 06]

The added benefits of the decision aid being delivered by a professional and having the discussion about future place of care can help to clarify views and opinions on the issues that need to be considered in decision-making:

'Talking to you has made it clear to me that my responses are very mixed' [Wife of person with dementia; 012]

When should a decision aid be used?

All participants were very clear that information about future place of care should not be delivered at the point of diagnosis:

> *'I think that will worry people a lot... they will think the worst... let the patient get used to it a little bit, let it sink in a bit you know and see what progress' [Wife of person with dementia; 015].*

> *'I mean it can't be right at the beginning, you can't cope with it' [Wife of person with dementia; 012]*

Carers felt that waiting until the dementia had progressed and also relying on the knowledge of expertise to raise the issue was important:

> *'Well not on diagnosis, I think you know, maybe after 2 or 3 years' [Husband of person with dementia; 011]*

> *'That's probably a judgement of the memory clinic... a major part of the remit of the clinician in the memory clinic you know is to just assess how things are going I think by directly asking the question and also trying to look beyond the answers... people probably are reluctant to say 'oh it's all getting a bit much for me' and perhaps you have to draw that out of them a bit more' [Husband of person with dementia; 014]*

Discussion

Our qualitative study was the first to interview people with dementia about their experiences of decision-making around care homes and to interview people at the time of this decision rather than prospectively or retrospectively. The nature of the illness means people with dementia may have had difficulty remembering how decisions were taken; however, where we could, we spoke to carer-care recipient dyads, so we could explore the process from both perspectives. Most of the people with dementia we interviewed did not feel part of decision-making about place of care. Some preferred their family to decide for them but others felt excluded and even humiliated by not being included. Carers often reported that it was not possible to involve the person with dementia in the decision due to their lack of understanding of the issues necessitating a move.

The people with dementia reported a strong desire to continue living in their own homes. Carers recognized and echoed this desire however concerns around the safety and ability of people with dementia were often such that it was not possible. Support both from other family members and healthcare professionals was sought and valued, but consistent with other research reports, many carers found difficulty in negotiating the complicated healthcare system [12]. The deteriorating healthcare status of carers can be a crucial factor in the decision making process.

None of the people interviewed drew on discussions about place of care earlier in the dementing illness or advanced statements when making their decision. Perhaps the dementia was diagnosed too late for the person to be involved in planning care, or perhaps opportunities for discussions that might have eased the difficulty of later decision-making were missed. Carers often find planning difficult, and Advanced Care Plans (ACPs) have not been widely taken up [13]. Decision making for the long term can be avoided due to fear of confrontation with the care recipient and fears of this uncertain future [14]. Sometimes there are too many uncertainties to draw up definitive plans for the future. The unanimity that this planning should not take place near the time of diagnosis certainly reduces the window to make these advance decisions.

We recognize that there may be limitations of the findings due to sample size however in a review of over 500 qualitative research projects sample sizes, the most common were 20 and 30 [15]. We only interviewed people who had capacity, so did not include people with more severe dementia, although we did speak to relatives of people with more severe dementia. We interviewed only those able to speak fluent English so we cannot comment on the needs of those who do not. Ethnicity has been found to affect the decision to look after an individual with dementia at home resulting in presenting later to services, with carers reporting issues with filial piety and obligation (Chang et al., [16, 17]) and that there is often a lack of culturally appropriate facilities (in terms of language and food) [18].

Conclusions

The decisions about placement were often made at a point in the illness when insight into risks and abilities to stay at home were often lost. Consequently, people with dementia were sometimes unable to contribute fully or at all to the decision, whilst carers felt overwhelmed and distressed. Participants described the decision as a balance between the importance of remaining in a familiar environment and the need to reduce unacceptable levels of risk or accidents at home. The effect on wider family and carers' health were considered. Support from healthcare professionals was appreciated but sometimes confusing to access or provided inadequate assistance to those making this pivotal decision about place of care for people with dementia. Our findings would support development of an intervention to help people with dementia and their families and carers have facilitated discussions about these issues of future place of care earlier in the illness, when decisions about whether, when and where placement might be needed in

future could be shared. Such a resource should be interactive and individual, completed with a healthcare professional so there is opportunity for clarification of thoughts and a written record. It should encourage the use of family and other resources and signpost to these and include what might change for both the person with dementia and their carer and alternatives to care homes. Our findings are not only important for healthcare professionals in terms of how they facilitate conversations with carers but equally important for healthcare commissioners responsible for assigning appropriate amounts of professional resource to provide this level of carer support. Further research should focus on developing and testing a tool for healthcare professionals to facilitate decision-making with carers of people with dementia around future place of care.

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
KL, CC and GL all contributed to the design of the study. KL conducted all qualitative interviews. KL and SR independently analyzed the data for themes and agreed on a coding frame. All authors revised the manuscript critically and approved the final version for publication.

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Appendix 4: Phase one: Ethics approval letter

NHS
Health Research Authority

National Research Ethics Service

NRES Committee London - Bloomsbury
HRA NRES Centre Manchester
Barlow House 3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7815
Facsimile: 0161 625 7299

13 January 2014

Dr Claudia Cooper
Senior Clinical Lecturer
University College London
UCL Mental Health Sciences Unit
Charles Bell House
67-73 Riding House Street
W1W 7EJ

Dear Dr Cooper

Study title:	**The DECIDE Study: Dementia carers making informed decisions. Version 1**
REC reference:	**14/LO/0012**
IRAS project ID:	**122658**

The Research Ethics Committee reviewed the above application at the meeting held on 08 January 2014. Thank you for attending to discuss the application, together with Miss Kathryn Lord.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Dr Ashley Totenhofer, nrescommittee.london-bloomsbury@nhs.net.

Ethical opinion

1. Dr Cooper and Miss Lord were informed there was an observer present and queried whether this was OK. Dr Cooper and Miss Lord stated it was.

2. The committee queried what order the events will take place in; are the Health Care Professionals or Patients and Carers interviewed first.

   Miss Lord stated the Patients and Carers are interviewed first, although the Health Care Professionals will be used to recruit these. Once they have feedback from these groups they will amend the CHOICE leaflet and then give it to the Health Care Professionals. They will then run the Health Care Professional focus groups.

3. The committee queried who will first approach the potential participants.

   Miss Lord stated that they will be given the Participant Information Sheet by their clinician and then the interviews will be carried out by her.

   You stated that most will be recruited through your clinic and you will check with them that they are happy to be approached by Kathryn.

4. The committee queried whether posters would be used in the recruitment process.

   Miss Lord stated they would be.

5. The committee commented that the CHOICE leaflet is quite long and queried whether it would be possible to go through the whole thing in an hour.

   You stated you will only be looking at the Care Home section in this study.

6. The committee queried whether they will be looking for an emotional response or something more structured.

   Miss Lord stated they hope to see both.

7. The committee queried how is mild dementia defined in the study.

   You stated they will all be recruited through the dementia clinic and will have mild dementia.

8. The committee queried who will check their suitability to be included.

   You stated it will be their clinician.

   The committee commented that it may be helpful to have a more rigorous definition in the inclusion/exclusion criteria.

9. The committee stated there was a typo in the Poster.

10. The committee noted there was a letter regarding the insurance indemnity for the study but not a copy of the actual certificate.

    Miss Lord stated she could get that from UCL.

11. The committee commented that it can be quite hard to get transcripts reviewed by the participants and queried whether it may be better to have them look at an amended CHOICE leaflet.

    You stated you have used this process in the past and found that between a third and a quarter have responded with corrections.

12. The committee queried whether there was a lone worker policy.

    Miss Lord stated she will follow the UCL policy.

13. The committee stated the Participant Information Sheet needed to state that the interview tapes would be erased once they had been transcribed.

14. The committee commented that it is nice to see a supervisor attend with their student.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, **subject to the conditions specified below.**

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. In the Information Sheets please add the following sentence to the section titled 'What will I have to do?' – The recordings will be deleted once they have been transcribed. This should come after the fifth sentence in the Carer and Patient sheets and the sixth sentence in the Health Care Professional sheet.

2. Please correct the lower speech bubble on the Poster so it reads 'Would you like us to hear your…'

3. Please provide a copy of the Universities Insurance Indemnity certificate.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Advertisement	Poster - Version 1	14 October 2013
Covering Letter		29 November 2013
Interview Schedules/Topic Guides	Carers - version 1	15 October 2013
Interview Schedules/Topic Guides	Patient - Version 1	15 October 2013
Interview Schedules/Topic Guides	HCP - Version 1	15 October 2013
Investigator CV	Claudia Cooper	
Investigator CV	Gill Livingston	
Investigator CV	Kathryn Lord	
Letter from Sponsor	UCL/UCLH	20 November 2013
Other: Research Materials - CHOICE Study Leaflets		
Participant Consent Form: Carers	1	14 October 2013
Participant Consent Form: Patient	1	19 November 2013
Participant Consent Form: HCP	1	15 October 2013
Participant Information Sheet: Carers	1	14 October 2013
Participant Information Sheet: Patients	1	19 November 2013
Participant Information Sheet: HCP	1	24 October 2013
Protocol	1	14 October 2013
Questionnaire: Decisional Conflict Scale	Validated	
REC application	3.5	26 November 2013

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

14/LO/0012 **Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

[redacted]

Signed on behalf of:
Reverend James Linthicum
Vice-Chair

Email: nrescommittee.london-bloomsbury@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: Dr Clara Kalu – UCL

Mrs Angela Williams - Camden & Islington NHS Foundation Trust

Dr Kathryn Lord – UCL

Professor Gill Livingston - UCL

NRES Committee London - Bloomsbury

Attendance at Committee meeting on 08 January 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Joe Brierley	Consultant Intensivist	No	Chair
Ms Sally Doganis	Executive Producer and Media Consultant	Yes	
Dr Rashmi Gandhi	Neonatal registrar	Yes	
Professor Faith Gibson	Clinical Professor of Children and Young People's Cancer Care	No	Alternate Vice-Chair
Ms Claire Khalil	Pharmacist	No	
Dr Rachel L Knowles	Clinical Research Fellow	Yes	
Dr Leah Li	Statistician	No	
Dr Vincenzo Libri	Consultant in Clinical Pharmacology	Yes	
Reverend Jim Linthicum	Lay member - Hospital Chaplain	Yes	Vice-Chair – Chaired the meeting
Michelle McPhail	Lecturer in Management Studies	Yes	
Dr Katie Elizabeth Myers Smith	Health Psychologist	No	
Mrs Rosa Pizer	Lay member - Retired Teacher/Volunteer Jewish Chaplain	Yes	
Mr Roger Selby	Lay member - Retired Solicitor	Yes	
Ms Nabila Youssouf	Clinical Trials Manager	No	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Nicola Joseph	Observer
Dr Ashley Totenhofer	REC Manager

Written comments received from:

Name	*Position*
Professor Faith Gibson	Clinical Professor of Children and Young People's Cancer Care

Appendix 5: Phase one: R&D approval letter

noclor NHS

Bedford House, 3rd Floor
125-133 Camden High Street
London, NW1 7JR

Tel: 020 3317 3045
Fax: 020 7388 8530/5758
www.noclor.nhs.uk

07 February 2014

Miss Kathryn Lord
UCL Mental Health Sciences Unit
Charles Bell House
67-73 Riding House Street
London W1W 7EJ

Dear Kathryn,

Employer: ***University College London***
Accountable to: **Dr Claudia Cooper**

This letter confirms your right of access to conduct research throughout the trusts identified in the box below, and in the case of multi-project letters of access, in the box(es) in the appendix page(s), for the purpose and under the terms and conditions set out in page 2 & page 3.

For R&D office only: please complete the table below. If the researcher is undertaking more than one project at any one time, please complete the table(s) for the remaining projects in the Appendix page(s).		**Project 1 of 1**
Study Title: The DECIDE Study: Dementia carers making informed decisions. **R&D reference:** 122658 **REC reference:** 14/LO/0012		
Letter of access duration: 2 years and 8 months	**Start date: 07/02/2014**	**End date: 30/10/2016**
Camden & Islington NHS Foundation Trust Barnet Enfield & Haringey Mental Health Trust -- -- --	-- -- -- -- -- --	
If any information on this document is altered after the date of issue, this document will be deemed INVALID		

Yours sincerely,

[redacted]

Mabel Sall
Research Management & Governance Manager

R&D office will provide the corresponding trust(s) with copy of agreement. It is the researcher's responsibility to provide their substantive employer with a copy of this document

Appendix 6: Phase one: Patient information sheet

Camden and Islington NHS
NHS Foundation Trust

UCL MENTAL HEALTH SCIENCES UNIT
FACULTY OF BRAIN SCIENCES
BLOOMSBURY CAMPUS

UCL

Participant Information Sheet

The DECIDE Study: Dementia carers making informed decisions (Student Project)

Patient Interviews

Introduction
We would like to invite you to take part in a research project which is being conducted about family carers who may have to make decisions for relatives or friends who have memory problems. Before you decide whether to take part it is important that you understand why the research is being done and what this study will involve. Please take time to read the following information carefully and discuss it with relatives, friends, and your clinician if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
The purpose of our project is to develop an information guide for carers of people with memory problems and health care professionals to use when making decisions about living arrangements and place of care for people with memory problems.

Why have I been invited?
We understand that you have memory problems and therefore may have had or will have experience of trying to make decisions with your relatives or friends. The sorts of decisions may be around your living arrangements and future place of your care.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do you will be given this information sheet to keep. You are free at any point to withdraw without giving a reason. Withdrawal or non-participation will not affect your care in any way.

What will happen to me if I take part?
You will be asked to take part in an individual interview with the researcher at your home or if you prefer at University College London.

What do I have to do?
The interview will last around one hour and will take place at a time and location to suit you. We will ask you about your experience in making a decision specifically when it comes to future living arrangements and place of care. We want you to tell us about the particular circumstances, what it was that made you come to that decision and what would have made a difference to the situation. We will also show you some information leaflets we have already created and ask for your feedback on these including the content, appearance, length and whether you think they would help you with decision making. These one to one interviews will be tape recorded, and anonymously written up. The recordings will be deleted once they have been transcribed. You will be offered the

opportunity to review your own transcript for comment and alteration. Following all participant interviews we will create an information resource which will be sent to the Alzheimer's Society User Reference Group for feedback.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get might help improve the support offered to carers of people with memory problems and help health care staff discuss living arrangements and place of care with families in the future.

Are there any disadvantages from taking part?

We do not anticipate that there will be any disadvantages to taking part except for the inconvenience of making time for the interview, but it is possible that some topics discussed concerning the stresses of caring may be upsetting. If this is the case you can speak to your local mental health service or ring the Alzheimer's Society helpline **0300 222 1122** which is open from 9am to 5pm Monday to Friday.

Will my taking part in the project be kept confidential?

All interviews are confidential and anonymous so your name and your relative/friend's name will not be disclosed to anyone else and neither will you be identified in any report or publication.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Claudia Cooper who is the Chief Investigator for the research and is based at UCL Mental Health Sciences Unit. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Should you wish to contact an independent team, please do contact the Patient Advice and Liaison Service (PALS) on Tel: 020 3317 3117

What will happen to the results of the project?

We intend to publish results in relevant conference proceedings and publications and as an information guide for health care professionals and carers. Please tell the researchers if you would like a copy of any publications and we would be happy to send this to you. You will not be identified in any report or publication.

Who is organising and funding this project?

This project is part of a PhD. The PhD studentship is funded by UCL IMPACT Award and co-funded by UCL Mental Health Sciences Unit who are organising the research.

Who has reviewed the project?

All proposals for research using human subjects are reviewed by an Ethics Committee before they can proceed. This proposal was reviewed by London-Bloomsbury National Research Ethics Service (Ref No: 14/LO/0012).

How to contact the research team

If you have any further queries please do not hesitate to contact Kathryn Lord on Tel: 0207 679 9716 or email: k.lord@ucl.ac.uk You may also contact either Dr Claudia Cooper (Chief Investigator) on Tel: 020 7679 9435 or email: Claudia.cooper@ucl.ac.uk or Professor Gill Livingston (Academic Supervisor) on Tel: 0207 679 9716 or email: g.livingston@ucl.ac.uk

You will be given a copy of the information sheet and a signed consent form to keep.
Thank you for considering taking part or taking time to read this sheet.

Appendix 7: Phase one: Carer information sheet

Camden and Islington NHS
NHS Foundation Trust

UCL MENTAL HEALTH SCIENCES UNIT
FACULTY OF BRAIN SCIENCES
BLOOMSBURY CAMPUS

UCL

Participant Information Sheet

The DECIDE Study: Dementia carers making informed decisions (Student Project)

Carer Interviews

Introduction
We would like to invite you to take part in a research project which is being conducted about family carers who have to make decisions for relatives or friends who have memory problems. Before you decide whether to take part it is important that you understand why the research is being done and what this study will involve. Please take time to read the following information carefully and discuss it with relatives, friends, and your clinician if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
The purpose of our project is to develop an information guide for carers of people with memory problems and health care professionals to use when making decisions about living arrangements and place of care for people with dementia.

Why have I been invited?
We understand that you have a relative or friend with memory problems and therefore may have had or will have experience of trying to make decisions for someone else. The sorts of decisions may be around living arrangements and future place of care for your friend or relative.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do you will be given this information sheet to keep. You are free at any point to withdraw without giving a reason. Withdrawal or non-participation will not affect your relative/friend's care in any way.

What will happen to me if I take part?
You will be asked to take part in an individual interview with the researcher at your home or if you prefer at University College London.

What do I have to do?
The interview will last around one hour and will take place at a time and location to suit you. We will ask you about your experience in making a decision for someone with memory problems specifically when in comes to future living arrangements and place of care. We want you to tell us about the particular circumstances, what it was that made you come to that decision and what would have made a difference to the situation. We will also show you some information leaflets we have already created and ask for your feedback on these including the content, appearance, length and whether you think they would help you with decision making. These one to one interviews will be tape recorded, and anonymously written up. The recordings will be deleted once they have been

transcribed. You will be offered the opportunity to review your own transcript for comment and alteration. Following all participant interviews we will create an information resource which will be sent to the Alzheimer's Society User Reference Group for feedback.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get might help improve the support offered to carers of people with dementia and help health care staff discuss living arrangements and place of care with families in the future.

Are there any disadvantages from taking part?

We do not anticipate that there will be any disadvantages to taking part except for the inconvenience of making time for the interview, but it is possible that some topics discussed concerning the stresses of caring may be upsetting. If this is the case you can speak to your local mental health service or ring the Alzheimer's Society helpline **0300 222 1122** which is open from 9am to 5pm Monday to Friday.

Will my taking part in the project be kept confidential?

All interviews are confidential and anonymous so your name and your relative/friend's name will not be disclosed to anyone else and neither will you be identified in any report or publication.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Claudia Cooper who is the Chief Investigator for the research and is based at UCL Mental Health Sciences Unit. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Should you wish to contact an independent team, please do contact the Patient Advice and Liaison Service (PALS) on Tel: 020 3317 3117

What will happen to the results of the project?

We intend to publish results in relevant conference proceedings and publications and as an information guide for health care professionals and carers. Please tell the researchers if you would like a copy of any publications and we would be happy to send this to you. You will not be identified in any report or publication.

Who is organising and funding this project?

This project is part of a PhD. The PhD studentship is funded by UCL IMPACT Award and co-funded by UCL Mental Health Sciences Unit who are organising the research.

Who has reviewed the project?

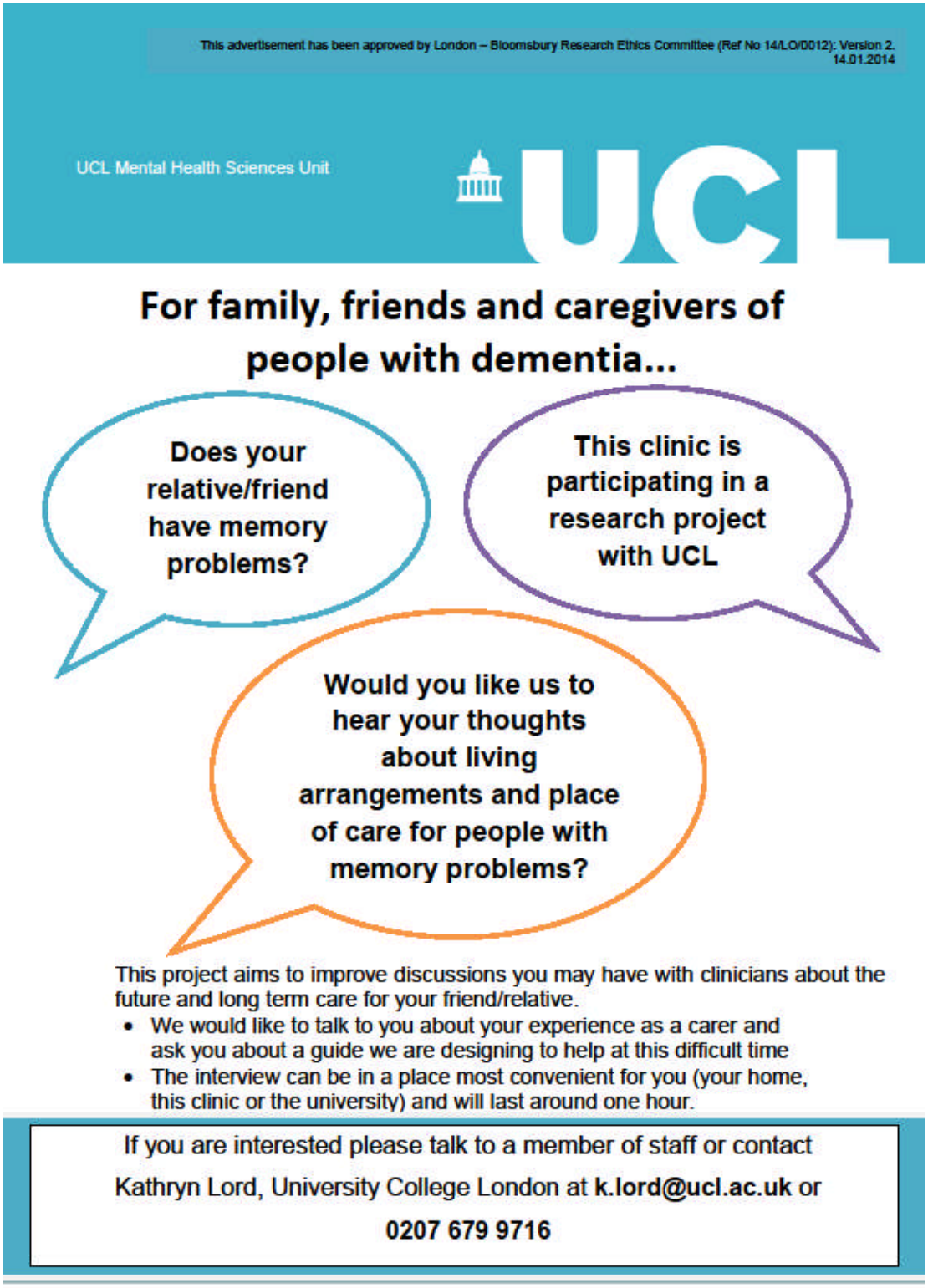
All proposals for research using human subjects are reviewed by an Ethics Committee before they can proceed. This proposal was reviewed by London-Bloomsbury National Research Ethics Service (Ref No: 14/LO/0012).

How to contact the research team

If you have any further queries please do not hesitate to contact Kathryn Lord (PhD Student) on Tel: 0207 679 9716 or email: k.lord@ucl.ac.uk You may also contact either Dr Claudia Cooper (Chief Investigator) on Tel: 020 7679 9435 or email: Claudia.cooper@ucl.ac.uk or Professor Gill Livingston (Academic Supervisor) on Tel: 0207 679 9716 or email: g.livingston@ucl.ac.uk

You will be given a copy of the information sheet and a signed consent form to keep.
Thank you for considering taking part or taking time to read this sheet.

Appendix 8: Phase one: Recruitment poster



Appendix 9: Phase one: Patient consent form

Camden and Islington NHS
NHS Foundation Trust

UCL MENTAL HEALTH SCIENCES UNIT
FACULTY OF BRAIN SCIENCES
BLOOMSBURY CAMPUS

UCL

Participant Identification Number: _____

CONSENT FORM

The DECIDE Study: Dementia carers making informed decisions (Student Project)

Patient interviews

Please tick box

1. I confirm that I have read and understood the information sheet (Version 2_14.01.14) for the above study. I have had the opportunity to consider the information and ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I understand that relevant sections of data collected during the study, may be looked at by responsible individuals from University College London or from the NHS Trust, where it is relevant to my taking part in this research. ☐
4. I agree that my interview comments can be audio-taped and transcribed. ☐
5. I understand that anonymised quotes from the interview may be included in publications. Researchers will remove personal details to ensure that I cannot be identified from any quotation. ☐
6. I agree to take part in the above study. ☐

Name of Participant..... Signature..... Date.....

Researcher..... Signature..... Date.....

Kathryn Lord, PhD Student
Mental Health Sciences Unit
University College London
Charles Bell House
67-73 Riding House Street
London W1W 7EJ
k.lord@ucl.ac.uk
020 7679 9716

Appendix 10: Phase one: Carer consent form

Camden and Islington NHS
NHS Foundation Trust

UCL MENTAL HEALTH SCIENCES UNIT
FACULTY OF BRAIN SCIENCES
BLOOMSBURY CAMPUS

UCL

Participant Identification Number: _____

CONSENT FORM

The DECIDE Study: Dementia carers making informed decisions (Student Project)

Carer interviews

Please tick box

1. I confirm that I have read and understood the information sheet (Version 2_14.01.14) for the above study. I have had the opportunity to consider the information and ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I understand that relevant sections of data collected during the study, may be looked at by responsible individuals from University College London or from the NHS Trust, where it is relevant to my taking part in this research. ☐
4. I agree that my interview comments can be audio-taped and transcribed. ☐
5. I understand that anonymised quotes from the interview may be included in publications. Researchers will remove personal details to ensure that I cannot be identified from any quotation. ☐
6. I agree to take part in the above study. ☐

Name of Participant..... Signature..... Date.....

Researcher..... Signature..... Date.....

Kathryn Lord, PhD Student
Mental Health Sciences Unit
University College London
Charles Bell House
67-73 Riding House Street
London W1W 7EJ
k.lord@ucl.ac.uk
020 7679 9716

Appendix 11: Phase one: Patient interview topic guide

UCL MENTAL HEALTH SCIENCES UNIT
FACULTY OF BRAIN SCIENCES
BLOOMSBURY CAMPUS

The DECIDE Study: Dementia carers making informed decisions (Student Project)

Patient semi-structured interview schedule

Thank you for agreeing to this interview, we are here to listen to your experiences as someone with memory problems and how you make decisions about your care.

This interview is about improving the understanding of the needs of carers and people with memory problems in making decisions around living arrangements and place of care. The aim of the study is to create an information guide for clinicians to improve facilitation of this decision making process with families.

We would like you tell us about how you make decisions, particularly in relation to living arrangements and place of care and provide feedback about leaflets we have previously created in this area for use in our guide.

This interview is going to be audio recorded; whatever you tell me will be anonymised for the purposes of the study so you or any other individuals/services you mention will not be identifiable. However if you do disclose any information that you or someone else is being harmed I will ask your permission to disclose the information to my supervisor. We respect confidentiality but cannot keep it a secret if anyone is being seriously harmed.

If at any point during the interview you feel that you need to stop or leave the room please do tell me.

Living arrangements

Q. Where do you currently live? How long have you lived there? And do you enjoy living there?
- Do you see any down sides or have any worries about where you live?

Q. Do your relatives/friends have any worries about where you currently lives?
- Do they have different views than yours?
- Are there different views within the family?
- Are there things that might change how you feel about this?

Prompts:
- Loneliness risks, distance from family, amount of care available.

Q. Do you sometimes think you would be better off living somewhere different?
- Have you talked to anyone about this and was that helpful?
- Are there other things that have helped you think about this?
- Is there information that you wished you'd had?
- Are there things that have been unhelpful?
- What would help you make decisions about this?

Q. Looking back at your experiences, is there a time when it would have been helpful for you to have been approached to talk about this?
- When did you want the information?

Q. *[If the person has already made decisions about future living arrangements]*
- Did you feel supported?
- Did you find these difficult? Why so?

CHOICE Leaflets

I'm now going to show you some leaflets that were designed after to speaking with carers of people with memory problems in a previous study carried out at UCL (separate document).

Q. What to do think of these leaflets?
Prompts
- Content, appearance, length

Q. Would these have helped/do you think they may help when making decisions about your place of care and living arrangements?

Q. At what point do you think you would like to receive this information? And from whom?

Q. How could we improve these?

Decisional Conflict Scale (DCS)

I'm now going to show you a scale – in the future, we are hoping to ask carers to complete this before and after they have been given the toolkit we just showed you to see if it changes any of their responses (separate document). This has been carried out with patients and carers in previous work.

Q. Do you think this tool could be used in relation to decisions about place of care?
Q. What do you like/dislike about the tool?
- Length, format, wording etc

Q. Would you be happy to complete this scale?

Other

Q. Before we finish, is there anything else you would like to mention that we have not already covered?

That is the end of the interview. Thank you for your help. We will now type up your interview and send it back to you for checking/comments. Once we have interviewed all our participants, we will be amending our guide and will also send this to you for any further comments you may have.

Appendix 12: Phase one: Carer interview topic guide

UCL MENTAL HEALTH SCIENCES UNIT
FACULTY OF BRAIN SCIENCES
BLOOMSBURY CAMPUS

The DECIDE Study: Dementia carers making informed decisions (Student Project)

Carer semi-structured interview schedule

Thank you for agreeing to this interview, we are here to listen to your experiences as a carer and your role in the decision making process in terms of your relatives care.

This interview is about improving the understanding of the needs of carers in making decisions around living arrangements and place of care for their relative. The aim of the study is to create an information guide for clinicians to improve facilitation of this decision making process.

We would like you tell us about your role as carer in the decision making process, particularly in relation to living arrangements and place of care and provide feedback about leaflets we have previously created in this area for use in our guide.

This interview is going to be audio recorded; whatever you tell me will be anonymised for the purposes of the study so you or any other individuals/services you mention will not be identifiable. However if you do disclose any information that you or someone else is being harmed I will ask your permission to disclose the information to my supervisor. We respect confidentiality but cannot keep it a secret if anyone is being seriously harmed.

If at any point during the interview you feel that you need to stop or leave the room please do tell me.

Living arrangements

Q. Where does your friend/relative currently live? How long have they lived there? And do they enjoy living there?
- Does [insert name] see any down sides or have any worries about where they live?

Q. Do you have any worries about where your friend/relative currently lives?
- Do you and [insert name] have different views?
- Are there different views within the family?
- Are there things that might change how you feel about this?

Prompts:
- Loneliness risks, distance from family, amount of care available.

Q. Do you sometimes think they would be better off living somewhere different?
- Have you talked to anyone about this and was that helpful?
- Are there other things that have helped you think about this?
- Is there information that you wished you'd had?
- Are there things that have been unhelpful?
- What would help you make decisions about this?

Q. Looking back at your experiences, is there a time when it would have been helpful for you to have been approached to talk about this?
- When did you want the information?

Q. *[If the person has already made decisions]*
- Did you feel supported?
- Did you find these difficult? Why so?

CHOICE Leaflets

I'm now going to show you some leaflets that were designed after to speaking with other carers in a previous study carried out at UCL (separate document).

Q. What to do think of these leaflets?
Prompts
- Content, appearance, length

Q. Would these have helped/do you think they may help when making decisions about place of care for your friend/relative?

Q. At what point do you think you would like to receive this information? And from whom?

Q. How could we improve these?

Decisional Conflict Scale (DCS)

I'm now going to show you a scale – in the future, we are hoping to ask carers to complete this before and after they have been given the toolkit we just showed you to see if it changes any of their responses (separate document). This has been carried out with patients and carers in previous work.

Q. Do you think this tool could be used in relation to decisions about place of care for your friend/relative?
Q. What do you like/dislike about the tool?
- Length, format, wording etc

Q. Would you be happy to complete this scale?

Other

Q. Before we finish, is there anything else you would like to mention that we have not already covered?

That is the end of the interview. Thank you for your help. We will now type up your interview and send it back to you for checking/comments. Once we have interviewed all our carers, we will be amending our guide and will also send this to you for any further comments you may have.

Appendix 13: CHOICE factsheets

UCL DEPARTMENT OF
MENTAL HEALTH SCIENCES

UCL

Deciding about a Care Home?

How can I make a decision as to whether my relative needs a care home?

Some families decide never to use a care home. Most people want to care at home for as long as possible and services can help. People often feel guilty about admission of a family member to a care home. Whatever plans you have, bear in mind that circumstances change.

"And my husband said "Promise me one thing, you'd never put me into a home", and I said, I promise." Wife

It is often helpful for you to discuss the decision with other family members, a health professional or social worker. Sometimes it is easier for others to see if a care home is needed.

"And because I had… somebody [brother] close to me saying [a care home], he could see it from a different angle to me and… [then] I decided." Daughter

"At the end of respite, the man in charge in the home said "How can you take him home? It always needs two people to see to him." So, I decided to leave him there…" Wife

"The GP thought that it was quite irresponsible, the idea that we should wait until my husband had an accident or something very serious happened." Wife

Staying at home can be impossible if your relative does not accept care.

"He refused to have anyone looking after him at home." Wife

Sometimes it can be unsafe to keep them at home.

"He was very aggressive... Every time I wanted to do something, he pushed me…" Wife

It can become impossible for families to continue to manage at home, especially when there are other demands such as work and young children, or the carer has their own health problems.

CHOICE: CARE HOME?

BupaFoundation
The Medical Research Charity

Section 5a

DECIDING ABOUT A CARE HOME?

"Once my wife went into care, it took the pressure off me. It wouldn't have been so bad if I'd been retired and I could look after her 24/7." Husband

"I've got quite bad arthritis so there's no way I could physically look after her…" Son

How can I decide on a care home?

Making a decision about moving your relative into a care home is very difficult and an emotional process. Use available information, help and support. Friends and family can also help make the decision.

"It's not very easy… to make a decision… on somebody else's behalf, it's even worse." Wife

Family members sometimes decide to live in a care home and take an active part in the choice.

"[My mum] had chosen to go there, she just went in there, she had a lovely room." Daughter

Often people are no longer able to choose at the point they need a care home. Your choice depends on you and your relatives' needs and priorities. Remember you can ask the manager for the home inspection reports ***(also available on the regulatory bodies' websites).***

"It's within walking distance… so that it would be easy to bring her home…" Son

"The television wasn't on all the time… residents are sitting in small groups. They encourage people to talk to each other; it really had a very pleasant feel…" Wife

"I was looking for a home which [was] both residential and nursing, in case my husband needs nursing later… he doesn't have to be moved." Wife

Staff are very important.

"The staff were very outgoing and friendly, it was the way they interacted with the residents…" Wife

If you belong to a religious or secular community organisation, they may have connections to care homes.

"We went to a Jewish care home, which was very important to me." Wife

What happens after my relative goes into a care home?

You're still family and involved after they go into a care home.

"As your relative becomes less communicative, you almost become their eyes and ears… you know your family member very well." Daughter

CHOICE: CARE HOME?

DECIDING ABOUT A CARE HOME?

What financial help is available?

Care homes are means tested. Organisations such as Alzheimer's Society can provide information.

"The cost was an issue… I looked at all the information available on the Internet, contacted Alzheimer's Society and so forth…" Wife

Things to THINK about

- Circumstances change. Many carers found that despite their previous view that they would never consider a care home, they were left with no choice.
- Caring for a relative is difficult. Talk to the social or memory service about your options. Getting more help may prevent needing a care home.
- A care home can become the right decision when your own health or the health of your relative deteriorates or there are other competing demands. It may become unsafe for them to continue living at home.
- Family or professionals may be able to help you make the decisions.
- When choosing a care home, look for features such as location, staff interaction with residents and activities for residents.
- Care homes can sometimes be found through links with secular and religious community organisations.
- Residential care is means tested. Financial advice is available through organisations such as Alzheimer's Society and Age UK.

RESOURCES FOR CARERS

Resources for carers:

1. **Age UK** (amalgamation of "Age Concern" and "Help the Aged")
   www.ageuk.org.uk
   0800 169 65 65

2. **Alzheimer's Society**
   www.alzheimers.org.uk/factsheets
   0845 3000 336

3. **Admiral Nurses Helpline**
   www.www.dementiauk.org
   0845 257 9406

4. **Advance Directives**
   www.direct.gov.uk/en/Governmentcitizensandrights/Death Preparation/DG_10029683

5. **Carers Direct**
   www.nhs.uk/carersdirect
   0808 802 0202

6. **Citizens Advice Bureau**
   www.citizensadvice.org.uk
   0845 050 5250

7. **Carers Emergency Scheme**
   www.carersuk.org/Information/Findinghelp/EmergencySchemesList

8. **Carers UK**
   www.carersuk.org
   020 7490 8818

9. **Dignity in Dying**
   www.dignityindying.org.uk
   0870 777 7868

10. **DVLA**
    www.dft.gov.uk/dvla
    0300 790 6806

11. **Elderly Accommodation Counsel**
    www.housingcare.org
    020 7820 1343

12. **Hartford Foundation**
    www.thehartford.com/alzheimers/index.html
    00 11 860 547 5000

13. **Pick's Disease Support Group**
    www.pdsg.org.uk
    0845 458 3208

14. **Power of Attorney** (Office of The Public Guardian)
    www.publicguardian.gov.uk
    0300 456 0300

15. **Social Services**
    www.direct.gov.uk/en/DisabledPeople/HealthAndSupport/MentalHealth/index.htm

16. **Specialised Early Care for Alzheimer's**
    www.specal.co.uk
    01993 822 129

17. **The Leveson Centre for the Study of Ageing, Spirituality and Social Policy**
    www.leveson.org.uk/levesoncentre index.htm
    01564 778 022

18. **The Probate Service**
    www.hmcourts-service.gov.uk/infoabout/civil/probate/index.htm
    0845 30 20 900

These fact sheets were produced by Professor Gill Livingston, Dina Rickman, Shilpa Bavishi, Claudia Cooper, Monica Manela and other team members.

Appendix 14: DECIDE manual: Version one

The DECIDE toolkit for family / friend carers

Section 1: Where to live in the future

Section 2: Useful contact

Section 3: Summary

- This toolkit is based on what family carers and people with memory problems told us about how they make decisions on where they should live and be cared for in the future.
- Keep in mind that there is rarely a single correct answer. Each decision that you make will be influenced by your own individual circumstances.

DECIDE: Version 1: 08.07.14

Section 1: Where to live in the future

Memory loss and dementia can affect several areas of a person's life, making it difficult to function as usual.

The changes that occur might affect a person's needs in terms of their living accommodation.

It is important to think about where your relative may live in the future and understand what options are available.

Can you tell me any worries you are having about where your relative lives at the moment?

1.

2.

3.

4.

What circumstances might lead to a change in our living situation?

Following a diagnosis of dementia, there may be a number of scenarios that mean someone's living situation needs adjusting. It may be that your relative with dementia becomes ill or you are no longer able to care for their needs alone.

> *"We're coping pretty well at the moment but you know in years to come it could, you know it will probably get worse."* Husband

Some carers have expressed concerns about deterioration in their own health which would mean they could no longer care for their relative.

> *"That is something that worries me, if I get worse, who is going to look after him? That's my main worry."* Wife

Do you have any health concerns that you have not discussed with a health care professional?

What options are available to help me at home?

There are a number of services available that may help your relative to live at home.

Have you ever considered any of the following? If not do you think they might help?

Day Centre:
Your local day centre is…

Befrienders:
Speak to Age UK

Carers coming into your home:
How many times a day?

One option is to make adjustments to your current house to make caring easier.

What adjustments do you think may help you care at home?

Have you considered any of the following:

- Hand rails
- Stair lifts

These can be arranged by Social Services

Notes:

If you or your relative is not happy with a service you may be able to change this.

What help is available for carers in decision making?

You can ask for help and advice in making decisions from family and friends as well as voluntary organisations and professional services.

The Alzheimer's Society and Age UK, offer services including meeting with others in similar situations.

- Local carers group details:

Respite care is a short-term care option as a temporary arrangement from the person's usual care. This is often useful if carers feel they are in need of a break.

Carers are entitled to a certain amount of respite. Discuss the benefits of this here.

How can I make a decision about moving my relative from their own home?

Given the nature of dementia, there may be uncertainty about the future and so bear in mind that any decisions made may change again in the future.

"You can make a decision but it's not the last decision, you might have to change it again. And so you know it can be flexible and it will move, it will change."
Daughter

"The other thing is who knows how long it's going to last as an option as well you know, it might not be forever, it just depends how mum gets on really in the future, the next few years."
Daughter

Making decisions for relatives can be a very stressful and difficult thing to do, especially if this concerns a change in their accommodation.

Try to include the person with dementia in the discussions around this wherever possible and try to consider their prior wishes.

Have you and your relative ever discussed where they might live?

How can I make a decision as to whether my relative needs a care home?

Some families decide never to use a care home. Most people want to care at home for as long as possible. People often feel guilty about admission of a family member to a care home.

It is often helpful for you to discuss the decision with other family members, a health professional or social worker. Sometimes it is easier for others to see if a care home is needed.

Try to think about the advantages and disadvantages of all other types of accommodation.

- Sheltered accommodation

- Residential care home

- Nursing care home

It can often be very difficult and emotional to know when the 'right' time to move your relative is. Some carers report waiting until a crisis occurred before they were able to make the decision.

> *"It was going to be a crisis that was going to make something happen, to have to make that decision on a day to day basis about a change is too hard, when do you do it? At what stage do you suddenly say this is enough, I can't handle it any more."* Daughter

Talking about the various options with your relative, family and health care professionals may help prepare you if your relative does need a change in accommodation.

What financial help is available?

Care homes are means tested. Organisations such as Alzheimer's Society and Age UK can provide information.

You or your relative may also be eligible for various benefits or discounts following a diagnosis of dementia such as Attendance Allowance and Carers Allowance.

Be sure to get up to date information from your GP, memory service or voluntary organisations about what you are entitled to.

End of toolkit

Section 3: Useful contacts

1. Age UK (combination of "Age Concern" and "Help the Aged")
www.ageuk.org.uk
0800 169 6565
Age UK is the country's largest charity dedicated to helping everyone make the most of later life. They provide information or advice on anything from health to housing.

2. Alzheimer's Society
www.alzheimers.org.uk/factsheets
0300 222 1122
The Alzheimer's Society provides information to help with living with dementia: from understanding diagnosis and assessment to dealing with financial challenges you may encounter.

3. Admiral Nurses Helpline
www.www.dementiauk.org
0845 257 9406
Admiral Nurses are mental health nurses specialising in dementia. Admiral Nurses are available to support families throughout the dementia journey. They provide family carers with the tools and skills to best understand the condition, as well as emotional and psychological support through periods of transition.

4. Citizens Advice bureau
www.adviceguide.org.uk/england.htm
08444 111 444
The Citizens Advice bureau provides free, independent, confidential and impartial advice to everyone on their rights and responsibilities. They provide information on anything from benefits to healthcare.

5. Carers UK
www.carersuk.org
0808 808 7777
Carers UK offer advice, information and support for carers. They also have an online support network for carers and organise local carer support groups.

6. Compassion in Dying

http://www.compassionindying.org.uk/

0800 999 2434

Compassion in Dying is a national charity that supports people at the end of life to have what they consider to be a good death by providing information and support around their rights and choices.

7. Elderly Accommodation Counsel

www.housingcare.org

020 7820 1343

A charity run site providing free advice on elderly care, including specialist directories & information on nursing homes and residential care homes, as well as sheltered housing, extra care housing and retirement villages, across the UK.

8. Camden Care Choices

http://camdencarechoices.camden. gov.uk/

London borough specific information and advice on a range of topics including caring, needs assessments and available local services.

Section 3: Summary

It is important to think about what the person you care for would have wanted when they were able to decide.

- Circumstances change. Many carers found that despite their previous view that they would never consider a care home, they were left with no choice
- It may be helpful to discuss with your relative where they would want to live in the future if their health deteriorates.
- Family, friends and professionals can support you to make these decisions.
- Caring for a relative is difficult. Talk to the social or memory service about your options. Getting more help may prevent needing a care home.
- There are lots of services available for carers, including respite care in a care home if you are in need of a break.
- If you are worried that something may happen to you, you can discuss plans for your relative with your family and make a decision for this eventuality.
- Residential care is means tested. Financial advice is available through organisations such as Alzheimer's Society and Age UK. The Internet can be a valuable source of information.
- A care home can become the right decision when your own health or the health of your relative deteriorates or there are other competing demands. It may become unsafe for them to continue living at home.
- Remember that decisions may change over time and can be flexible to suit your wishes as the disease progresses.

This resource was produced by Kathryn Lord, Prof. Gill Livingston and Dr. Claudia Cooper. Many thanks to participants of the research project and feedback from memory clinic staff and the Alzheimer's Society.

DECIDE: Version 1: 08.07.14

Appendix 15: Phase one: Healthcare professional information sheet

UCL MENTAL HEALTH SCIENCES UNIT
FACULTY OF BRAIN SCIENCES
BLOOMSBURY CAMPUS

Camden and Islington NHS
NHS Foundation Trust

UCL

Participant Information Sheet

The DECIDE Study: Dementia carers making informed decisions (Student Project)

Health care professional Focus groups / Interviews

Introduction
We would like to invite you to take part in a research project. We are approaching you because we understand that you have experience in the support and care of people with dementia and their carers.

What is the purpose of the study?
The purpose of our project is to develop an information guide for carers of people with memory problems and health care professionals to use when making decisions about living arrangements and place of care for people with dementia.

Why have I been invited?
We understand that you work for one of the organisations that are supporting this research. They are Camden and Islington NHS Foundation Trust and Barnet, Enfield and Haringey Mental Health Trust. We are inviting health care professionals who work with people with dementia and their carers to participate.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do you will be given this information sheet to keep. You are free at any point to withdraw without giving a reason. Withdrawal or non-participation will not affect your relative/friend's care in any way.

What will happen to me if I take part?
You will be asked to take part in one discussion group with other health care professionals in our memory service. If you are unable to attend this group meeting you are welcome to participate in an individual interview with the researcher at a more convenient time/location.

What do I have to do?
The focus group or interview will last approximately one hour and lunch refreshments will be provided. There will be two researchers there to help the discussion and make sure everyone is heard. The discussion will be tape recorded so we make sure that we do not miss anything that is said. The discussion will cover your experiences of facilitating discussions with family carers about living arrangements and place of care for people with dementia. We will also show you an information guide we have already created following input from carers and ask for your feedback on this including the content, appearance, length and whether you think they would help you with facilitating this decision making and if they could be used in practice. These focus groups or one to one interviews will be tape recorded, and anonymously written up. The recordings will be deleted once they have been transcribed. You will be offered the opportunity to review your own transcript for comment and alteration.

Following all participant interviews we will create an information resource which will be sent to the Alzheimer's Society User Reference Group for feedback.

What are the possible benefits of taking part?
We cannot promise the study will help you but the information we get might help improve the support offered to carers of people with dementia and help health care staff discuss living arrangements and place of care with families in the future.

Are there any disadvantages from taking part?
We do not anticipate that there will be any disadvantages to taking part except for the inconvenience of making time for the interview, but it is possible that some topics discussed concerning the stresses of caring may be upsetting. If this is the case you can speak to your local mental health service or ring the Alzheimer's Society helpline **0300 222 1122** which is open from 9am to 5pm Monday to Friday.

Will my taking part in the project be kept confidential?
All interviews are confidential and anonymous so your name and your relative/friend's name will not be disclosed to anyone else and neither will you be identified in any report or publication.

What if there is a problem?
If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Claudia Cooper who is the Chief Investigator for the research and is based at UCL Mental Health Sciences Unit. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Should you wish to contact an independent team, please do contact the Patient Advice and Liaison Service (PALS) on Tel: 020 3317 3117

What will happen to the results of the project?
We intend to publish results in relevant conference proceedings and publications and as an information guide for health care professionals and carers. Please tell the researchers if you would like a copy of any publications and we would be happy to send this to you. You will not be identified in any report or publication.

Who is organising and funding this project?
This project is part of a PhD. The PhD studentship is funded by UCL IMPACT Award and co-funded by UCL Mental Health Sciences Unit who are organising the research.

Who has reviewed the project?

All proposals for research using human subjects are reviewed by an Ethics Committee before they can proceed. This proposal was reviewed by London-Bloomsbury National Research Ethics Service (Ref No: 14/LO/0012).

How to contact the research team

If you have any further queries please do not hesitate to contact Kathryn Lord on Tel: 0207 679 9716 or email: k.lord@ucl.ac.uk You may also contact either Dr Claudia Cooper (Chief Investigator) on Tel: 020 7679 9435 or email: Claudia.cooper@ucl.ac.uk or Professor Gill Livingston (Academic Supervisor) on Tel: 0207 679 9716 or email: g.livingston@ucl.ac.uk

You will be given a copy of the information sheet and a signed consent form to keep. Thank you for considering taking part or taking time to read this sheet.

Appendix 16: Phase one: Healthcare professional consent form

Camden and Islington NHS
NHS Foundation Trust

UCL MENTAL HEALTH SCIENCES UNIT
FACULTY OF BRAIN SCIENCES
BLOOMSBURY CAMPUS

UCL

Participant Identification Number: _____

CONSENT FORM

The DECIDE Study: Dementia carers making informed decisions (Student Project)

Health Care Professionals Focus Group/Interview

Please tick box

1. I confirm that I have read and understood the information sheet (Version 2, 14.01.14) for the above study. I have had the opportunity to consider the information and ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I understand that relevant sections of data collected during the study, may be looked at by responsible individuals from University College London or from the NHS Trust, where it is relevant to my taking part in this research. ☐
4. I agree that my interview comments can be audio-taped and transcribed. ☐
5. I understand that anonymised quotes from the interview may be included in publications. Researchers will remove personal details to ensure that I cannot be identified from any quotation. ☐
6. I agree to take part in the above study. ☐

Name of Participant..... Signature..... Date.....

Researcher..... Signature..... Date.....

Kathryn Lord, PhD Student
Mental Health Sciences Unit
University College London
Charles Bell House
67-73 Riding House Street
London W1W 7EJ
k.lord@ucl.ac.uk
020 7679 9716

Appendix 17: Phase one: Healthcare professional topic guide

UCL MENTAL HEALTH SCIENCES UNIT
FACULTY OF BRAIN SCIENCES
BLOOMSBURY CAMPUS

The DECIDE Study: Dementia carers making informed decisions (Student Project)

Health Care Professionals Focus Group/Interview Schedule

Thank participants for agreeing to take part in the focus group or interview.

Assure participants that everything discussed during the focus group/interview is confidential and although we are recording the session and taking notes so that we don't miss anything important, the data will be anonymised so that no individual can be identified.

The purpose of this focus group/interview is to get your input into the development of a toolkit for clinicians to improve facilitation of decision making around long term care for carers of people with dementia.

We have already interviewed a group of carers and have modified the CHOICE leaflets following their input. We would like to show you this newly adapted toolkit and base the discussion around this.

If at any point during the discussion you feel that you need to stop or leave the room please do tell me.

Information guide

We envisage this guide would be for people you see in clinic that worry if home is the right place for the person with dementia any more.

Q. What are your initial thoughts on the guide? (Prompts to include feedback regarding length, design, content)

Q. When is most appropriate to raise and discuss this issue (living arrangements/place of care) with carers?

Q. What do you think are family carers main concerns around this topic area?

Q. Would they use this information guide?

- If not, what could we improve that would make you use it?
- Can you think of current clients that you could use it with?
- How often do you see yourself using it?

Q. Who do you think would be the best health care professional to use this guide/have these discussions with family members?

- How long do you think this discussion would take?

Q. Do you have any other feedback regarding layout, design, content etc.?

That is the end of the focus group/interview. Thank you for your help. We will now type the discussion and send it back to you for checking/comments. Following this we will be amending our information guide(where necessary) and will also send this to you for any further comments you may have.

Appendix 18: DECIDE manual: Version two

The DECIDE manual for family / friend carers

Section 1: Where to live in the future

Section 2: Useful contact

Section 3: Summary

- This manual is based on what family carers and people with memory problems told us about how they make decisions on where they should live and be cared for in the future.
- Keep in mind that there is rarely a single correct answer. Each decision that you make will be influenced by your own individual circumstances.

1

Section 1: Where to live in the future

Memory loss and dementia can affect several areas of a person's life, making it difficult to function as usual.

The changes that occur might affect a person's needs in terms of their living accommodation.

It is important to think about where your relative may live in the future and understand what options are available.

Do you have any worries about where your relative lives at the moment?

1.

2.

3.

4.

What circumstances might lead to a change in our living situation?

There may be a number of scenarios that mean someone's living situation needs adjusting. It may be that your relative with dementia becomes ill or you are no longer able to care for their needs alone.

> *"We're coping pretty well at the moment but you know in years to come it could, you know it will probably get worse."* Husband

Some carers have expressed concerns about deterioration in their own health which would mean they could no longer care for their relative.

> *"That is something that worries me, if I get worse, who is going to look after him? That's my main worry."* Wife

Do you have any health worries that may affect your ability to be a carer?

What options are available to help me at home?

There are a number of services available that may help your relative to live at home.

Have you ever considered any of the following?

Day Centre:
Note: How long and often? / Availability

Befrienders: Speak to Age UK
Note: Availability / Is this suitable?

Carers coming into your home:
Note: How often? / Resistance

One option is to make adjustments to your current house to make caring easier.

What adjustments do you think may help you care at home and maintain your relative's safety?

Speak to your health care professional about the following:

- Hand rails / raised toilet seat / Bed rails
- Stair lifts
- Key safe
- CarelineUK Service
  - *Personal emergency alarm*
- Assistive technology
  - Devices to help with things such as daily living, hearing and eyesight
  - Alarms, sensors (gas, water and heat), pill box alarms

If you or your relative is not happy with a service you may be able to change this.

What help is available for carers in decision making?

You can ask for help and advice in making decisions from family and friends as well as voluntary organisations and professional services.

The Alzheimer's Society and Age UK, offer services including meeting with others in similar situations.

- **Local carers group**
- **Dementia advisors / navigators**

Respite care is a short-term, temporary change from the person's usual care. This is useful if carers feel they need a break.

Carers are entitled to a certain amount of respite. Discuss the benefits of this here.

6

How can I make a decision about moving my relative from their own home?

Given the nature of dementia, there may be uncertainty about the future. Bear in mind that any decisions made may change again in the future.

"You can make a decision but it's not the last decision, you might have to change it again. And so you know it can be flexible and it will move, it will change."
Daughter

"The other thing is who knows how long it's going to last as an option as well you know, it might not be forever, it just depends how mum gets on really in the future, the next few years."
Daughter

Making decisions for relatives can be a very stressful and difficult.

Try to include the person with dementia in the discussions wherever possible and try to consider their prior wishes.

Have you and your relative ever discussed where they might live?

Where else could my relative live other than their own home?

Try to think about the advantages and disadvantages of all other types of accommodation.

- **Sheltered accommodation**

A scheme manager (a warden) lives onsite or offsite, and provide 24-hour emergency help through an alarm system. These self-contained flats often have communal areas and many run social events for residents.

- **Extra care housing**

This housing can allow more independence than living in a care home, as you would still live in a self-contained flat but the facility would provide 24 hour on-site care staffing.

- **Care home**

Care homes may provide personal care, such as meals and medication or nursing care such as medical care, some of which can specialise in dementia.

Some families decide never to use a care home. Most people want to care at home for as long as possible.

It can often be very difficult to know when the 'right' time to move your relative is. Some carers report waiting until a crisis occurred before they were able to make the decision.

> *"It was going to be a crisis that was going to make something happen, to have to make that decision on a day to day basis about a change is too hard, when do you do it? At what stage do you suddenly say this is enough, I can't handle it any more."* Daughter

Talking about the various options with others may help prepare you if your relative does need a change in accommodation.

What financial help is available?

You or your relative may also be eligible for various benefits or discounts following a diagnosis of dementia.

Care homes are means tested. Organisations such as Alzheimer's Society and Age UK can provide information.

Be sure to get up to date information from your GP, memory service or voluntary organisations about what you are entitled to.

- Attendance Allowance
  - Your relative with dementia could get money towards care.
- Carers Allowance
  - Is for people with a substantial caring role.
- Direct payments
  - These let you choose and buy the services you need yourself, instead of getting them from your council.
- Continuing care
  - Ongoing healthcare outside of a hospital funded by the NHS.

10

Summary of discussion

Here is a summary of things we have discussed today:

Section 2: Useful contacts

1. Age UK (combination of "Age Concern" and "Help the Aged")

www.ageuk.org.uk

0800 169 6565

Age UK is the country's largest charity dedicated to helping everyone make the most of later life. They provide information or advice on anything from health to housing.

2. Alzheimer's Society

www.alzheimers.org.uk/factsheets

0300 222 1122

The Alzheimer's Society provides information to help with living with dementia: from understanding diagnosis and assessment to dealing with financial challenges you may encounter.

3. Admiral Nurses Helpline

www.www.dementiauk.org

0845 257 9406

Admiral Nurses are mental health nurses specialising in dementia. They provide family carers with the tools and skills to best understand the condition, as well as emotional and psychological support through periods of transition.

4. Citizens Advice Bureau

www.adviceguide.org.uk/england.htm

08444 111 444

The Citizens Advice bureau provides free, independent, confidential and impartial advice to everyone on their rights and responsibilities. They provide information on anything from benefits to healthcare.

5. Carers UK

www.carersuk.org

0808 808 7777

Carers UK offer advice, information and support for carers. They also have an online support network for carers and organise local carer support groups.

6. Compassion in Dying

http://www.compassionindying.org.uk/

0800 999 2434

Compassion in Dying is a national charity that supports people at the end of life to have what they consider to be a good death by providing information and support around their rights and choices.

7. Elderly Accommodation Counsel

www.housingcare.org

020 7820 1343

A charity run site providing free advice on elderly care, including specialist directories & information on nursing homes and residential care homes, as well as sheltered housing, extra care housing and retirement villages, across the UK.

Section 3: Summary

Things to think about:

- It may be helpful to discuss with your relative where they would want to live in the future if their health deteriorates.
- Family, friends and professionals can support you to make these decisions.
- Circumstances change. Caring for a relative is difficult. Talk to the social or memory service about your options. Getting more help may prevent needing a care home.
- There are lots of services available for carers, including respite care in a care home if you are in need of a break.
- If you are worried that something may happen to you, you can discuss plans for your relative with your family and make a decision for this eventuality.
- Residential care is means tested. Financial advice is available through organisations such as Alzheimer's Society and Age UK. The Internet can be a valuable source of information.
- A care home can become the right decision when your own health or the health of your relative deteriorates or there are other competing demands. It may become unsafe for them to continue living at home.
- Remember that decisions may change over time and can be flexible to suit your wishes as the disease progresses.

This manual was produced by Kathryn Lord, Prof. Gill Livingston and Dr. Claudia Cooper. Many thanks to participants of the research project and feedback from memory clinic staff and the Alzheimer's Society.

Appendix 19: Phase two: RCT ethics approval letter

NHS
Health Research Authority
NRES Committee North East - Newcastle & North Tyneside 2
Room 001
Jarrow Business Centre
Rolling Mill Road
Jarrow
NE32 3DT

Telephone: 0191 428 3561

14 January 2015

Professor Gill Livingston
Professor in Psychiatry of Older People
University College London
Division of Psychiatry
Charles Bell House
67-73 Riding House Street
London
W1W 7EJ

Dear Professor Livingston

Study title:	**The DECIDE Study: Dementia carers making informed decisions: Phase Two. Version 1**
REC reference:	**15/NE/0015**
IRAS project ID:	**162996**

The Proportionate Review Sub-committee of the NRES Committee North East - Newcastle & North Tyneside 2 reviewed the above application on 13 January 2015.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Assistant Miss Kerry Dunbar, nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

To amend the participant information sheet to include:

"That if a disclosure of harm was made then that information would be passed on to the educational supervisor and the appropriate action would be taken".

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

Members requested confirmation on how they would establish:

a) That the patient themselves lack the capacity to make the decision about where they live.

Ms Kathryn Lord replied that they were not recruiting patients with dementia to the study and therefore do not need to establish their capacity. Nonetheless they were recruiting carers of people with moderate or severe dementia (MMSE <20) and whilst it was not assumed that all people with dementia would have lost capacity to make the decision for themselves, evidence suggests that at this stage of the illness this was likely the case. This study was concerned with exploring the conflict carer's face when making this decision for others.

b) That the carer/friend identified was the most appropriate person/person with the authority to make the decision about the patients living location.

Ms Lord replied that the carers/friends would be identified by the health care professionals within the memory clinics. Before recruitment commences they would explain to professionals that they were looking for the 'main carer' of the person with dementia who would have responsibility for other decision making on their behalf. If carers have Power of Attorney they were the decision maker for the person with dementia and they would recruit them to the study. If there was no Power of Attorney then the person with dementias Social Worker would be deemed the decision maker however in any instance the healthcare professional would be guided and advised by the 'main carer' i.e. closest family member and would only override the carers decision if they thought it caused the person with dementia harm therefore they would recruit this person as the carer. The researcher would also check with the potential participant before consent was obtained that they believe they were the most appropriate person.

Members enquired if the participants become distressed during the course of the interview, would any advice or assistance be immediately available from the researchers themselves

Ms Lord replied that in the unlikely event that participants do become upset whilst taking part in the study, the researcher would ask them if they want to have a break from the interview, continue or to stop. Having a break to talk about what might be distressing the participant and allow them time to gather themselves would be offered to all. The researcher would ensure participants know the contact details of the Alzheimer's Society and local PALS Service as detailed in the information sheet and also recommend they speak to their clinician within the memory service if they felt they need to. The researcher had extensive experience of conducting interviews with relatives of patients and patients with dementia in a number of areas including end of life care. If participants would like the researcher to mention their concerns that were

raised during the interview to the clinician within the local team then they would be happy to do so.

Members queried how would any distress/anxiety be detected during the telephone conversation and how would this be dealt with.

Ms Lord replied that as the one week follow up telephone conversation was for completion of the Decisional Conflict Scale and the evaluation of the DECIDE toolkit (structured questions) it may be that they would not know there was any anxiety or distress unless the participants choose to tell them directly. If they were very distressed it may be clear from their answers to the questions or their tone of voice. However as previously mentioned the researcher was very experienced at conducting interviews, including telephone interviews and if any distress or anxiety was detected similar steps to the answer to point 2 would take place, the researcher would ask them if they want to have a break from the interview, continue or to stop. The researcher would ensure participants know the contact details of the Alzheimer's Society and local PALS Service as detailed in the information sheet and also recommend they speak to their clinician within the memory service if they needed to. If participants would like the researcher to mention their concerns that were raised during the interview to the clinician within the local team then they would be happy to do so.

Members requested clarification if a deficiency of care either on the part of the carer or healthcare professionals was uncovered during the conversations, what actions would be taken.

Ms Lord replied that in the event of disclosure of information by participants the researcher would consult Gill Livingston (CI and academic supervisor) straight away. Gill was a consultant, in old age psychiatry with considerable experience in the field of dementia and would handle all reports according to safe guarding procedures and ensure the local services were made aware where necessary.

Members requested clarification on how would the participants be contacted after 10 weeks and how many times would contact be attempted before they were considered 'lost to follow-up'.

Ms Lord replied that all participants would be made aware that the follow up visits and one week and ten weeks after baseline. At the one week telephone interview they would remind them that they were due their follow up visit in 9 weeks and if possible schedule a time for this then. A letter confirming this visit would be sent to participants. They would contact participants via telephone one week before their 10 week follow up was due to arrange this. They would attempt to contact participants three times by telephone (as with previous studies) owing to the fact many carers could be working. If they fail to get a response by the third telephone call participants would be sent a letter asking them to contact the research team to schedule this visit if they would still like to participate. If there was no response to this they would ask the local services if they were aware of any reason why they should not contact the carer or for instance if they had moved house. If this elicits no response then they would be considered 'lost to follow up'.

Members requested clarification in the event of a disclosure of harm or intent to harm was made, what actions would be taken beyond informing the academic supervisor.

Ms Lord replied that the research team would be adhering to and following local safeguarding procedures and would ensure that local clinical teams know what was taking place.

Informed consent process and the adequacy and completeness of participant information

Members requested that the participant information sheet be amended to include more detail on the topics to be discussed, as was suggested in the IRAS form.

Ms Lord replied that they had added a paragraph explaining to the participants what the DECIDE toolkit was and what they would be asked in the qualitative interviews.

The Committee was satisfied with the amended document.

Members requested that the participant information sheet be amended to remove the statement "that if a disclosure of harm is made, then the researcher will ask the participants permission to relay this to their supervisor" and include a statement "that if a disclosure of harm was made then that information would be passed on to the educational supervisor and the appropriate action taken".

Ms Lord replied that this statement was in the Phase Two: Ten week follow up assessment and had been changed accordingly.

Suitability of supporting information

Member requested confirmation on what the 'HADS' questionnaire was and how was it to be used in this study.

Ms Lord replied that the 'HADS' was the 'Hospital Anxiety and Depression Scale' (Zigmond and Snaith, 1983). This scale would be carried out with carers in both the control and intervention group at all three assessments along with the Decisional Conflict Scale (Baseline, one week and 10 weeks). This is a self-completion questionnaire however if participants had any issues with eye sight or physical impairments that may not make this possible then they would offer to help complete it with them.

The Committee was satisfied with the responses given to the issues raised.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Certificate]	1	14 July 2014
Interview schedules or topic guides for participants [DECIDE_Baseline Assessment]	1	28 October 2014
Interview schedules or topic guides for participants [DECIDE 1 Week Follow Up]	1	28 October 2014
Interview schedules or topic guides for participants [10 week follow up]	V2.0	
IRAS Checklist XML [Checklist_06012015]		06 January 2015
IRAS Checklist XML [Checklist_06012015]		06 January 2015
Letter from sponsor [Insurance Confirmation Letter]	1	21 November 2014
Other [DECIDE Toolkit]	2	11 August 2014

Other [Covering Email]		12 January 2015
Participant consent form [Carers Consent Form]	1	27 October 2014
Participant information sheet (PIS) [Carer]	V2.0	12 January 2015
REC Application Form [REC_Form_06012015]		06 January 2015
Research protocol or project proposal [Phase 2 Protocol_V1_13.10.14]	1	13 October 2014
Summary CV for Chief Investigator (CI) [Gill Livingston CV]	1	20 November 2013
Summary CV for student [Kathryn Lord CV]	1	20 November 2013
Summary CV for supervisor (student research) [Claudia Cooper CV]	1	20 November 2013
Validated questionnaire [HADS]	1	15 December 2014
Validated questionnaire [DCS]	1	15 December 2014

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

15/NE/0015	Please quote this number on all correspondence

Yours sincerely

pp

[redacted]

Dr Jared Thornton
Chair

Email: nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers"

Copy to: *Smaragda Agathou, University College London*
Mrs Angela Williams, Camden & Islington NHS Foundation Trust

NRES Committee North East - Newcastle & North Tyneside 2

Attendance at PRS Sub-Committee of the REC meeting on 13 January 2015 via correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Chris Barron	ECMC & CTU Manager	Yes	
Mrs Ann Boardman	Retired Educationalist	Yes	
Dr Jared Thornton (Chair)	Clinical Trials Co-ordinator	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kerry Dunbar	REC Assistant

Appendix 20: Phase two: RCT R&D approval letter

noclor
RESEARCH SUPPORT

1st Floor, Bloomsbury Building
St Pancras Hospital
4 St Pancras Way
NW1 0PE

Tel: 020 3317 3045
Fax: 020 7685 5830/5798
www.noclor.nhs.uk

03 February 2015

Professor Gill Livingston
UCL, Division of Psychiatry,
Charles Bell House
67-73 Riding House Street
London W1W 7EJ

Dear Professor Livingston,

I am pleased to confirm that the following study has now received R&D approval and you may now start your research in **the trust(s) identified below**:

Study Title: The DECIDE Study: Dementia carers making informed decisions: Phase Two.
R&D reference: 162996
REC reference: 15/NE/0015

This NHS Permission is based on the REC favourable opinion given on **14 January 2015**

Name of the trust	Name of current LC	Date of permission issue(d)
Barnet Enfield & Haringey NHS Mental Health Trust	Dr Liz Sampson	03 February 2015
Camden & Islington NHS Foundation Trust	Prof. Gill Livingston	03 February 2015
East London NHS Foundation Trust	Dr Nick Bass	03 February 2015

If any information on this document is altered after the date of issue, this document will be deemed INVALID

Yours sincerely,

[redacted]
Research Operations Manager

Cc: Local Collaborator(s).
Kathryn Lord, Researcher
Research Site Research & Development Managers
Dave Wilson, Sponsor Contact

Appendix 21: Phase two: Carer information sheet

UCL DIVISION OF PSYCHIATRY
FACULTY OF BRAIN SCIENCES

Participant Information Sheet

The DECIDE Study: Dementia carers making informed decisions: Phase two

(Student Project)

Carer Interviews

Introduction
We would like to invite you to take part in a research project which is being conducted about family carers who have to make decisions for relatives or friends who have memory problems. Before you decide whether to take part it is important that you understand why the research is being done and what this study will involve. Please take time to read the following information carefully and discuss it with relatives, friends, and your clinician if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
The purpose of our project is to further develop and test an information guide for carers of people with memory problems to use when making decisions about living arrangements and place of care for people with dementia.

Why have I been invited?
We understand that you have a relative or friend with memory problems and therefore may have had or will have experience of trying to make decisions for someone else. The sorts of decisions may be around living arrangements and future place of care for your friend or relative.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do you will be given this information sheet to keep. You are free at any point to withdraw without giving a reason. Withdrawal or non-participation will not affect your relative/friend's care in any way.

What do I have to do?
An interviewer will come and visit you at home for an initial interview or if you prefer at University College London. The interview will last around one hour and will take place at a time and location to suit you. We will ask you for some personal details (age, where you and your friend/relative live) and to fill in a questionnaire about decision making for someone with memory problems when it comes to future living arrangements and place of care and also about how you are currently feeling.

You will then be allocated to one of two groups. This will happen automatically and we do not know who will be in which group. One half of people will be in the first group which involves getting the usual treatment, in this case being given a copy for the Alzheimer's

Society leaflet, and the other half of people will receive the DECIDE toolkit which the researcher will take you through at this initial interview.

The DECIDE toolkit was created after talking to carers, people with dementia and health care professionals about making decisions about where the person with dementia may live in the future. The toolkit is a 12 page manual that you will complete with the researcher and be able to keep for your own reference. It is designed for carers to think about any issues they may have with decision making about future place of care for their relative with dementia, consider some of the options available to them and places they can go for support.

At the end of this first visit we will then arrange a telephone follow up call with ALL participants to ask them a few questions about decision making. For those individuals in group two who received the DECIDE toolkit they will be asked for feedback about how they found this.

Finally, all participants will be followed up 10 weeks after their first visit to repeat the questionnaire on decision making and evaluation of the DECIDE toolkit (when used). At this point we would like to invite participants who are interested to take part in a short individual interview to understand more about the process of decision making for a person with memory problems. We want you to tell us what you thought of the toolkit, ways we could improve this and if this in any way helped with your decision making. These one to one interviews will be tape recorded, and anonymously written up. The recordings will be deleted once they have been transcribed.

The study will not involve the person with memory problems, nor be able to offer you any specific additional care. If you become unable to participate in the interviews or choose to withdraw from the study, we will keep and use the information we have already collected.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get might help improve the support offered to carers of people with dementia and help health care staff discuss living arrangements and place of care with families in the future.

Are there any disadvantages from taking part?

We do not anticipate that there will be any disadvantages to taking part except for the inconvenience of making time for the interview, but it is possible that some topics discussed concerning the stresses of caring may be upsetting. If this is the case you can speak to your local mental health service or ring the Alzheimer's Society helpline (**0300 222 1122**) which is open from 9.00am to 5.00pm Monday to Friday.

Will my taking part in the project be kept confidential?

All interviews are confidential and anonymous so your name and your relative/friend's name will not be disclosed to anyone else and neither will you be identified in any report or publication. If a disclosure of harm is made then that information will be passed on to the academic supervisor and the appropriate action will be taken.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Professor Gill Livingston who is the Chief Investigator for the research and is based at UCL Division of Psychiatry. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Should you wish to contact an independent team, please do contact the Patient Advice and Liaison Service (PALS) on Tel: xxxx xxxx xxxx (local details for each memory clinic will be added)

What will happen to the results of the project?

We intend to publish results in relevant conference proceedings and publications and as an information guide for health care professionals and carers. Please tell the researchers if you would like a copy of any publications and we would be happy to send this to you. You will not be identified in any report or publication.

Who is organising and funding this project?

This project is part of a PhD. The PhD studentship is funded by UCL IMPACT Award and co-funded by UCL Mental Health Sciences Unit who are organising the research.

Who has reviewed the project?

All proposals for research using human subjects are reviewed by an Ethics Committee before they can proceed. This proposal was reviewed by NRES Committee North East – Newcastle & North Tyneside 2 (REC Ref No: 15/NE/0015).

How to contact the research team

If you have any further queries please do not hesitate to contact Kathryn Lord (PhD Student) on Tel: 0207 679 9716 or email: k.lord@ucl.ac.uk. You may also contact Professor Gill Livingston (Chief Investigator) on Tel: 0207 679 9716 or email: g.livingston@ucl.ac.uk

You will be given a copy of the information sheet and a signed consent form to keep.
Thank you for considering taking part or taking time to read this sheet.

Appendix 22: Phase two: Carer consent form

UCL DIVISION OF PSYCHIATRY
FACULTY OF BRAIN SCIENCES

Participant Identification Number: _____

CONSENT FORM

The DECIDE Study: Dementia carers making informed decisions: Phase two (Student Project)

Carer interviews

Please initial box

1. I confirm that I have read and understood the information sheet (Version 3_14.01.15) for the above study. I have had the opportunity to consider the information and ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I understand that relevant sections of data collected during the study, may be looked at by responsible individuals from University College London or from the NHS Trust, where it is relevant to my taking part in this research. ☐
4. I agree that my interview comments can be audio-taped and transcribed. ☐
5. I understand that anonymised quotes from the interview may be included in publications. Researchers will remove personal details to ensure that I cannot be identified from any quotation. ☐
6. I agree to take part in the above study. ☐

Name of Participant..... Signature..... Date.....

Researcher..... Signature..... Date.....

Kathryn Lord, PhD Student
Division of Psychiatry
University College London
Charles Bell House
67-73 Riding House Street
London W1W 7EJ
k.lord@ucl.ac.uk
020 7679 9716

Appendix 23: Hospital Anxiety and Depression Scale (HADS)

HADS page 1

Read each item and tick the box next to the reply that comes closest to how you have been feeling in the past week.

1A **I feel tense or wound up:**

3 ☐ Most of the time

2 ☐ A lot of the time

1 ☐ From time to time, occasionally

0 ☐ Not at all

1D **I still enjoy the things I used to enjoy:**

0 ☐ Definitely as much

1 ☐ Not quite so much

2 ☐ Only a little

3 ☐ Hardly at all

2A **I get a sort of frightened feeling as if something awful is about to happen:**

3 ☐ Very definitely and quite badly

2 ☐ Yes, but not too badly

1 ☐ A little, but it doesn't worry me

0 ☐ Not at all

P.T.O. ⟫

2D **I can laugh and see the funny side of things:**

0 ☐ As much as I always could

1 ☐ Not quite so much now

2 ☐ Definitely not so much now

3 ☐ Not at all

3A **Worrying thoughts go through my mind:**

3 ☐ A great deal of the time

2 ☐ A lot of the time

1 ☐ From time to time but not too often

0 ☐ Only occasionally

3D **I feel cheerful:**

3 ☐ Not at all

2 ☐ Not often

1 ☐ Sometimes

0 ☐ Most of the time

4A **I can sit at ease and feel relaxed:**

0 ☐ Definitely

1 ☐ Usually

2 ☐ Not often

3 ☐ Not at all

4D **I feel as if I am slowed down:**

3 ☐ Nearly all the time

2 ☐ Very often

1 ☐ Sometimes

0 ☐ Not at all

5A **I get a sort of frightened feeling like 'butterflies' in the stomach:**

0 ☐ Not at all

1 ☐ Occasionally

2 ☐ Quite often

3 ☐ Very often

5D **I have lost interest in my appearance:**

3 ☐ Definitely

2 ☐ I don't take as much care as I should

1 ☐ I may not take quite as much care

0 ☐ I take just as much care as ever

6A **I feel restless as if I have to be on the move:**

3 ☐ Very much indeed

2 ☐ Quite a lot

1 ☐ Not very much

0 ☐ Not at all

P.T.O. 》

6D **I look forward with enjoyment to things:**

0 ☐ As much as I ever did

1 ☐ Rather less than I used to

2 ☐ Definitely less than I used to

3 ☐ Hardly at all

7A **I get sudden feelings of panic:**

3 ☐ Very often indeed

2 ☐ Quite often

1 ☐ Not very often

0 ☐ Not at all

7D **I can enjoy a good book or radio or TV programme:**

0 ☐ Often

1 ☐ Sometimes

2 ☐ Not often

3 ☐ Very seldom

The End

Total A =

Total D =

Appendix 24: Decisional Conflict Scale (DCS)

Decisional Conflict Scale (DCS)

Statement Format: 16 item, 5 response categories

My difficulty in making this choice

A. Which living arrangement option do you prefer? Please tick one box

	Relative remains at home, no care package
	Paid Carers
	Care Home
	Unsure

B. Considering the option you prefer, please answer the following questions:

	Strongly Agree [0]	Agree [1]	Neither Agree or Disagree [2]	Disagree [3]	Strongly Disagree [4]
1. I know which options are available to me.					
2. I know the benefits of each option.					
3. I know the risks and side effects of each option.					
4. I am clear about which benefits matter most to me.					
5. I am clear about which risks and side effects matter most.					
6. I am clear about which is more important to me (the benefits or the risks and side effects).					
7. I have enough support from others to make a choice.					
8. I am choosing without pressure from others.					
9. I have enough advice to make a choice.					
10. I am clear about the best choice for me.					
11. I feel sure about what to choose.					
12. This decision is easy for me to make.					
13. I feel I have made an informed choice.					
14. My decision shows what is important to me.					
15. I expect to stick with my decision.					
16. I am satisfied with my decision.					

PID:_____ Date:_____ Visit:_____

DCS Scoring

Total Score	
Uncertainty Sub Score	
Informed Sub Score	
Values Clarity Sub Score	
Support Sub Score	
Effective Decision Sub Score	

- **Total Score = 16 items** are summed, divided by 16, multiplied by 25.
  - Range from 0 [no decisional conflict] to 100 [extremely high decisional conflict].
- **Uncertainty Sub Score** = Items **10, 11, 12** are summed, divided by 3 and multiplied by 25.
  - Range from 0 [feels extremely certain about best choice] to 100 [feels extremely uncertain about best choice]
- **Informed Sub Score** = Items **1, 2, 3** are summed, divided by 3 and multiplied by 25.
  - Range from 0 [feels extremely informed] to 100 [feels extremely uninformed]
- **Values Clarity Sub Score** = Items **4, 5, 6** are summed, divided by 3 and multiplied by 25.
  - Range from 0 [feels extremely clear] to 100 [feels extremely unclear about personal values]
- **Support Sub Score** = Items **7, 8, 9** are summed, divided by 3 and multiplied by 25.
  - Range from 0 [feels extremely supported] to 100 [feels extremely unsupported]
- **Effective Decision Sub Score** = Items **13, 14, 15, 16** are summed, divided by 4 and multiplied by 25.
  - Range from 0 [good decision] to 100 [bad decision]

Appendix 25: Likert scale

Evaluation of the DECIDE toolkit (Intervention group only)

I would now like to ask you about the DECIDE toolkit. Please rate the following:

1. The quality of the information overall in the toolkit

|---|---|---|---|---|
1 2 3 4 5

Poor Fair Average Good Excellent

2. The relevance of the information to you/your relative in terms of living arrangements and future place of care

|---|---|---|---|---|
1 2 3 4 5

Little relevance Great relevance

3. This toolkit has useful to discuss living arrangements and future place of care for my relative with dementia

|---|---|---|---|---|---|---|---|---|---|
1 2 3 4 5 6 7 8 9 10

Not at all useful Extremely useful

Appendix 26: Phase two: Carer topic guide

The DECIDE Study: Dementia carers making informed decisions

Carer semi-structured interview schedule: Phase two

Intervention arm only

Thank you for agreeing to this interview, we are here to listen to your experiences of using the DECIDE toolkit and your role in the decision making process in terms of your relatives care. This interview is about improving the understanding of the needs of carers in making decisions around living arrangements and place of care for their relative. The aim of the study is to see if the toolkit can improve facilitation of this decision making process.

This interview is going to be audio recorded; whatever you tell me will be anonymised for the purposes of the study so you or any other individuals/services you mention will not be identifiable. However if a disclosure of harm was made then that information would be passed on to the educational supervisor and the appropriate action taken. *We respect confidentiality but cannot keep it a secret if anyone is being seriously harmed.*

If at any point during the interview you feel that you need to stop or leave the room please do tell me.

DECIDE Toolkit

Q. **What to do think of this toolkit?**
Prompts

- **Content, appearance, length**

Q. **Have these helped you make decisions about place of care for your friend/relative?**

- **If so, how? If not, why not?**

Q. **At what point do you think you would like to receive this information? And from whom?**

Q. **How could we improve these?**

Other

Q. **Before we finish, is there anything else you would like to mention that we have not already covered?**

That is the end of the interview. Thank you for your help.

Appendix 27: Skewness and kurtosis data

	DCS total score	Uncertainty score	Informed score	Values score	Support score	Effective decision score
Skewness	-0.475	.053	.019	.020	.400	-.215
Std. Error of Skewness	.369	.369	.369	.369	.369	.369
Kurtosis	.087	-.282	-.358	-.501	-.179	-.608
Std. Error of Kurtosis	.724	.724	.724	.724	.724	.724

Appendix 28: DECIDE manual: Version three

The DECIDE manual for family / friend carers

Section 1: Where to live in the future

Section 2: Useful contact

Section 3: Summary

- This manual is based on what family carers and people with memory problems told us about how they make decisions on where they should live and be cared for in the future.
- Keep in mind that there is rarely a single correct answer. Each decision that you make will be influenced by your own individual circumstances.
- Throughout please put your relative or friend with dementias name in the spaces provided e.g. _____ *(insert relatives name)*

Summary of discussion

Please complete after reading the manual.

Here is a summary of things we have discussed today:

2

Section 1: Where to live in the future

Memory loss and dementia can affect several areas of a person's life, making it difficult to function as usual.

The changes that occur might affect a person's needs in terms of their living accommodation.

It is important to think about where your relative may live in the future and understand what options are available.

Do you have any worries about where _____ *(insert relatives name)* lives at the moment?

1.

2.

3.

4.

What circumstances might lead to a change in our living situation?

There may be a number of scenarios that mean someone's living situation needs adjusting. It may be that _____ becomes ill or you are no longer able to care for their needs alone.

> *"We're coping pretty well at the moment but you know in years to come it could, you know it will probably get worse."* Husband

Some carers have expressed concerns about deterioration in their own health which would mean they could no longer care for their relative.

> *"That is something that worries me, if I get worse, who is going to look after him? That's my main worry."* Wife

Do you have any health worries that may affect your ability to be a carer for _____?

What options are available to help me at home?

There are a number of services available that may help _____ to live at home.

Have you ever considered any of the following?

Day Centre:
Note: How long and often? / Availability

Befrienders: Speak to Age UK
Note: Availability / is this suitable?

Carers coming into your home:
Note: How often? / Resistance

One option is to make adjustments to your current house to make caring easier.

What adjustments do you think may help you care at home and maintain _____ safety?

Speak to your health care professional about the following:

- Hand rails / raised toilet seat / Bed rails
- Stair lifts
- Key safe
- CarelineUK Service
  - *Personal emergency alarm*
- Assistive technology
  - Devices to help with things such as daily living, hearing and eyesight
  - Alarms, sensors (gas, water and heat), pill box alarms

If you or your relative is not happy with a service you may be able to change this.

What help is available for carers in decision making?

You can ask for help and advice in making decisions from family and friends as well as voluntary organisations and professional services.

The Alzheimer's Society and Age UK, offer services including meeting with others in similar situations.

- **Local carers group**
- **Dementia advisors / navigators**

Respite care is a short-term, temporary change from the person's usual care. This is useful if carers feel they need a break.

Carers are entitled to a certain amount of respite. Discuss the benefits of this here.

How can I make a decision about moving my relative from their own home?

Given the nature of dementia, there may be uncertainty about the future. Bear in mind that any decisions made may change again in the future.

> *"You can make a decision but it's not the last decision, you might have to change it again. And so you know it can be flexible and it will move, it will change."*
> Daughter

> *"The other thing is who knows how long it's going to last as an option as well you know, it might not be forever, it just depends how mum gets on really in the future, the next few years."*
> Daughter

Making decisions for relatives can be a very stressful and difficult.

Try to include _____ in the discussions wherever possible and try to consider their prior wishes.

Have you and _____ ever discussed where they might live?

Where else could my relative live other than their own home?

Try to think about the advantages and disadvantages of all other types of accommodation.

- **Sheltered accommodation**

A scheme manager (a warden) lives onsite or offsite, and provide 24-hour emergency help through an alarm system. These self-contained flats often have communal areas and many run social events for residents.

- **Extra care housing**

This housing can allow more independence than living in a care home, as you would still live in a self-contained flat but the facility would provide 24 hour on-site care staffing.

- **Care home**

Care homes may provide personal care, such as meals and medication or nursing care such as medical care, some of which can specialise in dementia.

Some families decide never to use a care home. Most people want to care at home for as long as possible.

It can often be very difficult to know when the 'right' time to move your relative is. Some carers report waiting until a crisis occurred before they were able to make the decision.

> *"It was going to be a crisis that was going to make something happen, to have to make that decision on a day to day basis about a change is too hard, when do you do it? At what stage do you suddenly say this is enough, I can't handle it any more."* Daughter

Talking about the various options with others may help prepare you if your relative does need a change in accommodation.

What financial help is available?

You or _____ may also be eligible for various benefits or discounts following a diagnosis of dementia.

Care homes are means tested. Organisations such as Alzheimer's Society and Age UK can provide information.

Be sure to get up to date information from your GP, memory service or voluntary organisations about what you are entitled to.

- Attendance Allowance
  - Your relative with dementia could get money towards care.
- Carers Allowance
  - Is for people with a substantial caring role.
- Direct payments
  - These let you choose and buy the services you need yourself, instead of getting them from your council.
- Continuing care
  - Ongoing healthcare outside of a hospital funded by the NHS.

Section 2: Useful contacts

1. Age UK (combination of "Age Concern" and "Help the Aged")
www.ageuk.org.uk
0800 169 6565
Age UK is the country's largest charity dedicated to helping everyone make the most of later life. They provide information or advice on anything from health to housing.

2. Alzheimer's Society
www.alzheimers.org.uk/factsheets
0300 222 1122
The Alzheimer's Society provides information to help with living with dementia: from understanding diagnosis and assessment to dealing with financial challenges you may encounter.

3. Admiral Nurses Helpline
www.www.dementiauk.org
0845 257 9406
Admiral Nurses are mental health nurses specialising in dementia. They provide family carers with the tools and skills to best understand the condition, as well as emotional and psychological support through periods of transition.

4. Citizens Advice Bureau
www.adviceguide.org.uk/england.htm
08444 111 444
The Citizens Advice bureau provides free, independent, confidential and impartial advice to everyone on their rights and responsibilities. They provide information on anything from benefits to healthcare.

5. Carers UK
www.carersuk.org
0808 808 7777
Carers UK offer advice, information and support for carers. They also have an online support network for carers and organise local carer support groups.

6. Compassion in Dying
http://www.compassionindying.org.uk/
0800 999 2434
Compassion in Dying is a national charity that supports people at the end of life to have what they consider to be a good death by providing information and support around their rights and choices.

7. Elderly Accommodation Counsel
www.housingcare.org
020 7820 1343
A charity run site providing free advice on elderly care, including specialist directories & information on nursing homes and residential care homes, as well as sheltered housing, extra care housing and retirement villages, across the UK.

Section 3: Summary

Things to think about:

- It may be helpful to discuss with your relative where they would want to live in the future if their health deteriorates.
- Family, friends and professionals can support you to make these decisions.
- Circumstances change. Caring for a relative is difficult. Talk to the social or memory service about your options. Getting more help may prevent needing a care home.
- There are lots of services available for carers, including respite care in a care home if you are in need of a break.
- If you are worried that something may happen to you, you can discuss plans for your relative with your family and make a decision for this eventuality.
- Residential care is means tested. Financial advice is available through organisations such as Alzheimer's Society and Age UK. The Internet can be a valuable source of information.
- A care home can become the right decision when your own health or the health of your relative deteriorates or there are other competing demands. It may become unsafe for them to continue living at home.
- Remember that decisions may change over time and can be flexible to suit your wishes as the disease progresses.

This manual was produced by Kathryn Lord, Professor Gill Livingston and Dr Claudia Cooper. Many thanks to participants of the research project and feedback from memory clinic staff and the Alzheimer's Society.

Appendix 29: IPDAS criteria checklist tables

Content: does the decision aid…			
Provide information about options in sufficient detail for decision-making?	Yes	No	N/A
a) Describe the health condition?	X		
b) List the options?	X		
c) List the options of doing nothing?	X		
d) Describe the natural course without options?		X	
e) Describe procedures?			X
f) Describe positive features [benefits]?	X		
g) Describe negative features of options [harms / side effects / disadvantages]?	X		
h) Include chances of positive / negative outcomes?			X
i) Does the patient decision aid describe what test is designed to measure?			X
j) Does the patient decision aid include chances of true positive, true negative, false positive, false negative test results?			X
k) Does the patient decision aid describe possible next steps based on test result?			X
l) Does the patient decision aid include chances the disease is found with / without screening?			X
m) Does the patient decision aid describe detection / treatment that would never have caused problems if one was not screened?			X
Present probabilities of outcomes in an unbiased and understandable way?			
a) Use event rates specifying the population and time period?			X
b) Compare outcome probabilities using the same denominator?			X

IPDAS criteria checklist for the DECIDE manual (version three): content

Content: does the decision aid…			
Present probabilities of outcomes in an unbiased and understandable way?	Yes	No	N/A
c) Outcome probabilities using the time period?			X
d) Compare outcome probabilities using the scale?			X
e) Describe uncertainty around probabilities [words, numbers, and diagrams]?			X
f) Allow the patient to select a way of viewing probabilities based on their own situation [e.g. age]			X
g) Place probabilities in context of other events?			X
h) Use both positive and negative frames [e.g. showing both survival and death rates]			X
Include methods for clarifying and expressing patients' values?			
a) Describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional and social effects?	X		
b) Ask patients to consider which positive and negative features matter most?	X		
c) Suggest ways for patients to share what matters most with others?	X		
Include structured guidance in deliberation and communication?			
a) Provide steps to make a decision?	X		
b) Suggest ways to talk about the decision with a health professional?	X		
c) Include tools [worksheet, question list] to discuss options with others	X		

IPDAS criteria checklist for the DECIDE manual (version three): development process

Development process: does the decision aid…			
Present information in a balanced manner?	Yes	No	N/A
a) Is the patient decision aid able to compare positive / negative features of options?	X		
b) Does the patient decision aid show negative / positive features with equal detail [fonts, order, display if statistics]?	X		
Have a systematic development process?			
a) Does the patient decision aid include developers' credentials / qualifications?	X		
b) Does the patient decision aid find out what users [patients, practitioners] need to discuss options?	X		
c) Does the patient decision aid have a peer review by patient / professional experts not involved in development and field testing?	X		
d) Has the patient decision aid been field tested with users / patients facing the decision?	X		
e) Has the patient decision aid been field tested with practitioners presenting options?		X	
f) The field tests with users [patients, practitioners] show the patient decision aid is acceptable?	X		
g) The field tests with users [patients, practitioners] show the patient decision aid is balanced for undecided patients?	X		
h) The field tests with users [patients, practitioners] show the patient decision aid is understood by those with limited reading skills?		X	
Use up to date scientific evidence that is cited in a reference section or technical document?			
a) Provide references to evidence used?	X		

IPDAS criteria checklist for the DECIDE manual (version three): development process

Development process: does the decision aid…			
Use up to date scientific evidence that is cited in a reference section or technical document?	Yes	No	N/A
b) Report steps to find, appraise, summarise evidence?	X		
c) Report date of last update?	X		
d) Report how often patient decision aid is updated?	X		
e) Describe quality of scientific evidence [including lack of evidence]?	X		
f) Use evidence from studies of patients similar to those of target audience?	X		
Disclose conflicts of interest?			
a) Report source of funding to develop and distribute the patient decision aid?	X		
b) Report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid?	X		
Use plain language?			
a) Is the patient decision aid written at a level that can be understood by the majority of patients in the target group?	X		
b) Is the patient decision aid written at a grade 9 or equivalent level or less according to readability score [SMOG or FRY]?		X	
c) Does the patient decision aid provide ways to help patients understand information other than reading [audio, video, or in-person discussion]?	X		

IPDAS criteria checklist for the DECIDE manual (version three): effectiveness

Effectiveness: Does the patient decision aid ensure decision-making is informed and values based?			
Decision processes leading to decision quality. The patient decision aid helps patients to…	Yes	No	N/A
a) Recognise a decision needs to be made?	Unknown		
b) Know options and their features?	X		
c) Understand that values affect decision?	X		
d) Be clear about option features that matter most?	X		
e) Discuss values with their practitioner?	Unknown		
f) Become involved in preferred ways?	Unknown		
Decision quality. The patient decision aid…			
a) Improves the match between the chosen option and the features that matter most to the informed patient?	X		

Appendix 30: DECIDE manual: Version three: Supporting information

LONDON'S GLOBAL UNIVERSITY

UCL

The DECIDE manual for family / friend carers

Supporting information: Version one (April 2016)

Developer's qualifications, affiliations and conflicts of interest

Kathryn Lord, University College London (UCL) PhD Student; BSc Psychology.

Gill Livingston, UCL Professor of old age psychiatry; MD FRCPsych.

Claudia Cooper, UCL Reader of old age psychiatry; PhD MRCPsych.

There are no conflict of interest issues for any of the developers and none of the authors have anything to gain or lose by the choices carers make after using the DECIDE manual.

Report of last update

The DECIDE manual (version three) was updated 04.04.2016

Version two update: 11.08.2014

Version one update: 08.07.2014

The DECIDE manual will be reviewed yearly for any appropriate updates or as required.

Funding for development and distribution

This decision aid was developed as part of KLs PhD. Funding for the PhD was obtained from University College London (UCL) Impact studentship and the Division of psychiatry.

Evidence used

The DECIDE manual is based on the CHOICE leaflets (Livingston *et al.*, 2010) and the development process published (Lord *et al.*, 2016).

Describe quality or lack of scientific evidence

There is limited, often conflicting, evidence about dementia outcomes for people who do and do not enter care homes, due both to a lack of research and the unpredictable nature of the disease. Due to this we are unable to provide probability or outcome information about options.

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